University of Alberta

APPLICATION OF QUALITY AUDIT IN ISO9001:2000 QUALITY MANAGEMENT SYSTEM

by

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ABSTRACT

In year 2000, ISO 9000 standards underwent a major. This change poses a serious challenge for both ISO9001:1994 registered companies and auditing professionals. This thesis provides solutions in quality auditing to help them to accommodate to this standard revision.

By applying process management principles, a process-based audit model is proposed to enable auditors to perform an ISO 9001:2000 audit. The whole quality system is evaluated as a set of interrelated processes. The process performance is measured against predetermined objectives and targets to identify possible improvement opportunities. The entire auditing process consists of top management audit and departmental audit to obtain the full picture of the quality system implementation and improvement.

Subsequently, auditing methodologies aiming to assist the organization transform its quality system to ISO9001:2000 are explored. Combined with the regular system audit, a perpetual self-audit model has been designed to serve this purpose. In this model, three levels of self-audits are proposed, namely micro-audit, milli-audit and nano-audit, that are implemented throughout the various organizational levels.

In the last part of this thesis, the process-based audit and the perpetual self-audit model were successfully implemented to transform the quality system of a case study company to conform to the ISO 9001:2000 standard.

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1.0 Introduction

1.1 Quality Audit

Since ISO 9001 standards were established in 1987, more and more companies, driven mainly by contract requirements and a desire for self-improvement, have been seeking third-party certification. As a result, quality audits performed by a variety of different types of auditors are being widely used to provide this certification. Quality audits are being performed by internal employees (First-Party Audits or Internal Audits), by current or potential customers (Second-Party Audits), or by an external auditing organization (Third-Party Audits). Each type of audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 9000:2000). A typical quality audit includes initiating the audit; conducting a document review; preparing for the on-site audit activities; conducting on-site audit activities; preparing, approving and distributing the audit report; and completing the audit (ISO 19011:2000). However, the widespread use of quality audits has led many people to question their value as a quality-assurance system, especially after the notorious Firestone/Bridgestone automobile tire recall. People began to question the value of quality system audits because they "failed to offer assurance to the public that products and services made by certified plants are safe and reliable" (Arter,2000a ;Daniels, 2000). In a traditional quality audit, auditors simply verify compliance with agreed-upon standards, without assessing the suitability of these standards or the effectiveness of the quality system to meet quality objectives (Karapetrovic & Willborn, 2001a; Beeler, 1999)

1.2 Year 2000 Revision of ISO 9001 Standards

The ISO 9000 standards are a set of international quality management system standards and guidelines. Since their initial publication in 1987, they have earned a global reputation as the basis for establishing quality management systems (ISO, 2003a). Up to the end of December 2002, at least 561,747 ISO 9000 certificates had been issued in 159 countries and economies (ISO, 2003b).In order to reflect modern management approaches and also to improve organizational practices, in December 2000, the International Organization for Standardization, known as ISO, overhauled the ISO 9000 quality-management standards and established three new standards:

- ISO 9001:2000 Quality management systems – requirements replaces the previous ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. It is intended to be applicable to all organizations, products and services. The revision of ISO 9001 and 9004 is based on eight quality management principles that reflect best management practices:

- Customer focus
- Leadership
- Involvement of people
- Process approach
- Systems approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

The Quality Management System covers, with the revised ISO 9001, the entire activities of an organization and provides assurance to customers that the quality processes of an organization are being addressed. It is now the only ISO 9000 to which third-party certification can apply (ISO 9001:2003c).

- ISO 9004:2000 Quality management systems – Guidance for performance improvement was developed with the revised ISO 9001 standard as a "consistent pair" of standards. The revised ISO 9001 clearly addresses the quality management system requirements for an organization, to demonstrate its capability to meet customer requirements and enhance customer satisfaction. The revised ISO 9004 is intended to lead beyond ISO 9001 to enhance satisfaction for interested parties.
- ISO 9000:2000 Quality management systems- fundamentals and vocabulary provides the terminology used in the previous two core standards. The objective was to use simple technically accurate terms, and to the greatest extent possible, rely on common dictionary definitions (ISO, 2003a). This standard also discusses the fundamental concepts related to quality management systems.
- ISO 19011:2000 Guidelines for quality and/or environmental management system auditing is the effort that ISO took to streamline both quality and environmental audit practices since these two audits share a lot of similarities. It outlines the principles of auditing, guidance on establishing and managing audit programs, guidance on conducting quality and/or environmental management system audits as well as on auditor competence.

ISO and the International Accreditation Forum (IAF) jointly agreed on a policy to ensure a smooth transition to the ISO 9000:2000 series. Under this policy, organizations certified to 1994 versions of ISO 9001, ISO 9002 or ISO 9003 were given a three-year deadline from the publication of the revised standards to obtain certification according to ISO 9001:2000. Therefore, after December 15 of 2003, companies certified according to the 1994 standards will lose their IAF accredited status (ISO, 2003d).

1.3 ISO 9000:2000 & Quality Audit

The 2000 revision to the ISO 9000 standards has had a huge impact on the quality audit, which requires a new approach to accommodate the change. As Russell (2000a) explained, the "more flexible and user friendly" new Quality Management System (QMS) standard has fewer mandated requirements and is not as easy to apply as the previous standard. In the previous 1994 version of the standard, most of the standard consisted of descriptive clauses prescribing documented procedures for carrying out relevant quality activities. Accordingly, a quality auditor just had to follow the document-to-practice audit trail to complete an audit. However, the 1994 standard required the auditee to have a gigantic documents system in order to obtain the certification. This kind of documents system is very ineffective, especially when changes to the current documents are deemed necessary. The document control staff have to go through several bureaucratic levels to have a change approved, and also must undergo the hassle of updating the previously distributed documents. Furthermore, the documents usually do not reflect the reality of the company's operations.

Another difficulty for an auditor is the process approach mandated by the ISO 9001:2000 standard. ISO 9001:2000 recognizes that the entire quality management system is made up of interrelated processes; therefore in addition to considering the process for product realization, the user must identify and manage the processes for the entire system as well (West, 2002a). This approach differs from that of the previous ISO 9001:1994 Quality Assurance System (QAS), in which the whole system was built upon several separate quality elements. How to apply a process approach to a quality audit is the question need to be answered to facilitate the implementation of the 2000 standard. Should an audit follow through the business processes if the auditor intends to provide value-added insight into the health of a quality system?

In short, the new ISO 9001:2000 standard poses a challenge to the current quality audit methodology.

1.4 Quality Audits & Self -Assessment

While a quality audit measures the effectiveness and achieved improvement of an organization's quality system against the requirements of ISO 9000 standard, a self-assessment provides "a framework for sustaining and stimulating a process for company-wide continuous improvement" (Van del Wiele et al., 2000). Self-assessment was originally defined as comprehensive, systematic and regular review of an organization's activities and results referenced against a business excellence model (BEM) (EFQM, 1999). Karapetrovic (2002) extends this definition to the regular ISO 9000 assessment field by stating, "[A self-auditor is] the process owner; in other words, the person or unit performing the work itself undertakes self-

evaluation" In contrast to the static "snapshot" quality audit which involves few employees, self-assessment (Van der Wiele et al., 1996)

- Provides the link between TQM and business objectives, and
- Generates ownership for quality improvement among line-managers and senior management.

Self-assessment forces managers and workers to examine their own areas of activity and develop improvement plans, thereby ensuring continuous improvement by a set of feasible actions. Therefore, self-assessment embodies the principle stipulated by total quality management, which requires a worker to be motivated and empowered in the workplace, facilitating an assessment of the worker's performance by the worker himself or herself. Coupled with the inherent advantages of a quality audit, in which an independent and objective system evaluation is performed, a self-audit raises the audit's functionality to a higher level by having the process owner take the initiative to continuously monitor and improve his or her own quality performance.

1.5 Organization of the Thesis

Chapter Two presents a literature review, which serves as the theoretical foundation for the proposed solution for implementing the ISO 9001:2000 QMS standard.

Chapter Three presents a process-based audit model to accommodate the implementation of the ISO 9001:2000 QMS standard. First, the structure of the relevant quality processes in the ISO 9001:2000 system is reviewed. Second, a two-

level audit methodology is presented. A detailed process-based audit checklist is attached to facilitate its application.

In Chapter Four, a perpetual audit model which exploits the benefits of both internal and self-audits is discussed. This model is disseminated into an audit at four hierarchical levels within the organization and is intended to provide incessant, self-motivated and in-depth assessment of a quality system for the purpose of continuous improvement.

Chapter Five presents a case study in which the two models proposed in the previous chapters are applied successfully to help a company upgrade its quality system to comply with the ISO 9001:2000 standard. This empirical evidence demonstrates these models' feasibility.

2.0 Literature Survey

2.1 Introduction

A survey of the existing literature has been conducted to improve the following aspects of the quality audit under the ISO 9001:2000 framework:

- The concept and methodology of the quality audit as well as the criticism of its inherent inadequacy
- The 2000 revision of ISO 9001 standards and its implications for the quality audit
- The proposed approaches for ISO 9001:2000 transition projects
- The concept and methodology of the self-audit and its possible integration into the quality audit

2.2 Quality Audits

2.2.1 Concepts

An audit is a long-established and well-respected activity in the accounting professions (Milles, 1989). The concept of quality evolved with the dominant importance of quality following the Industrial Revolution and the beginning of mass production. The literature provides various definitions of *Quality*. Its definition not only depends on the context which it applies to, but becomes more refined as the understanding of its implications improves. In the world of a quality auditor, *Quality* is termed as the "degree to which a set of inherent characteristics fulfils requirements" (ISO 9000:2000). Compared to its previous baffling definition in ISO8402:1994, this generic definition is simple to grasp and can be applied to any industrial setting. Milles' (1989) definition of quality is also very easy to comprehend.

Milles defines *Quality* as "putting the right product or service in the hands of the customer at the right time and at the right price". The definitions of "*Quality Management*" and "*Quality Assurance*" are very important to know. While sometimes they are used as synonyms, they refer to two different stages along the path of quality development. *Quality Management* refers to coordinated activities to direct and control an organization with regard to quality (ISO 9000:2000), while *Quality Assurance* is the part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000:2000). Dale (1999) describes *Quality Assurance* as the third and *Quality Management* as the ultimate level in the evolution of Total Quality Management. Although ISO 9001 changed its terminology from a "quality assurance" standard in 1994 to a "quality management" standard in 2000, the new standard is still a quality assurance system model (Gordon, 2002a & 2002b). A more accurate image of a quality management system is embodied in a business excellence model, such as the Malcolm Baldrige National Quality Award (MBNQA) and the European Quality Award (EQA), which measures a company's quality performance against leadership, people management, policy and strategy, resources, processes, people satisfaction, customer satisfaction, impact on society, and business results.

Quality audits emerged shortly after World War II and gained momentum when the military began issuing standards and specifications for products (Russell, 2000b). Table 2.1 presents a selection of the available definitions of the quality audit as well as comments on each definition's suitability for guiding a value-added audit process. In spite of its various definitions, a "quality audit" is a planned, objective,

and independent activity that evaluates, confirms or verifies a company's quality management system. It helps prevent problems in the organization being audited through the identification of activities liable to create future problems; hence, a quality audit provides the data for evaluating and improving the effectives of that system (Milles, 1989). Overall, by evaluating the documentation and resulting operations against predefined standards or other audit criteria, a quality audit generates an audit report, which, in some cases, requires specific corrective and/or preventive action for the purpose of continuous improvement. A quality audit consists of two types of assessment activities (Milles, 1989):

- *Suitability quality audit (Desktop Study or Document Review)*

  An audit or in-depth evaluation and comparison of the quality program (documentation) of the organization and specific elements (products, services, etc.) of the organization against the standards predetermined by the client
- *Conformity quality audit* (On-site audit)

  An audit or in-depth evaluation and comparison of the activities within the quality system against a predetermined quality program, i.e., against quality policies and procedures.

A successful quality audit has the following benefits for an organization (Russell, 2000b):

- Provides input for management decisions, so that quality problems and costs can be prevented or rectified
- Informs management of actual or potential risks
- Identifies areas of opportunity for continuous improvement

- Assesses personnel training effectiveness and equipment capability

Table 2.1
Comparison of audit definitions

Source	Definition	Comments
ISO 9000:2000	Systematic, independent and documented **process** for obtaining **audit evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled	A concise definition which includes independence and objectivity as audit principle.
ANSI/ASQC (1986)	Systematic examination of the acts and decisions of people with respect to quality in order to independently verify or evaluate and report degree of compliance to the operational requirements of the quality program, or the specifications or contract requirements of the product or service	Audit objectivity is not contained in the definition.
CSA(1981)	A human evaluation process to determine the degree of adherence to prescribed norms (criteria, standards) and resulting in a judgement	Here, an audit is not viewed as a documented activity.
ISO 10011(1990)	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives	It clarifies that the whole process is comprised of a suitability and compliance audit. However, objective evidence should be added for its significance to the audit results.
Russell(2000b)	A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are appropriate and effective and have been developed, documented, and implemented in accordance and in conjunction with specified requirements.	"in accordance " and "in conjunction " are similar concepts. "appropriate" is a murky concept which is very hard to assess in a quality audit.

- Provides visible management support of the quality program
- Verifies compliance to regulations

2.2.2 Audit Activities

Audit activities have several different classifications (ISO 19011, 2001; Sayle, 1997; Milles, 1989; ANSI/ASQC, 1986, CAN, 1981). Since no major difference exists among these proposed audit processes, hereafter Russell's (2000b) classification will be used.

STAGE 1: Audit Preparation

Following the initial contacts with the auditee, the audit process begins with the audit preparation. At this stage, working with the auditee, the registrar company determines the purpose and scope of the audit, determines the audit's feasibility (ISO 19011, 2001) and identifies the necessary resources (for example, the temporary office for the audit team) and the applicable reference standard (in this case, the ISO 9001:2000 standard). Upon the completion of the above pre-arrangement, the registrar company forms the audit team based on the audit's scope and the technical backgrounds of the available auditors. Lead auditor is selected to be in charge of the whole audit process. He or she then obtains and reviews the appropriate documentation, prepares (or appoints other members of the audit team to prepare) applicable checklists and other working papers, and determines the proper audit approach. As the major output of the audit preparation, an audit plan details the audit's purpose and scope, the standard and/or reference to be audited against, the audit team's members, the length and layout of the audit, and some logistic issues such as the data and location of the audit.

STAGE 2: ON-Site Audits

Upon the arrival of the audit team at the audit site, the lead auditor holds an initial meeting to introduce the audit team members, communicate the audit plan, explains the report's methodology, confirms the logistic arrangements, confirms the time for the closing meeting and daily briefings, and clarifies the role of the escort.

As the audit unfolds, the audit team gathers data via document/record examination, interviews, physical examinations, and observation of work activities to see if the documented quality system has been effectively established, implemented and maintained. Once the data-gathering phase is closed, the audit team starts to analyze and classify the evidence collected before presenting the audit's results. Analysis converts the raw data of the findings into collated information on what the actual quality performance is and what actions should be taken to improve it. Afterwards, a closing meeting with the auditee is held by the lead auditor, who presents a draft or preliminary audit report during the meeting.

STAGE 3: Audit Reporting

After the audit results have been reported at the closing meeting, the lead auditor formally communicates the audit results in a written audit report. It should provide correct and clear data for what will be effective as a management aid in addressing important organizational issues. This report serves the following functions (Russell, 2000b):

- It supplies information that verifies adherence to requirements or that initiates corrective action and system improvement.

- It guides management and its consultants in subsequent decisions and activities.
- It establishes a record of the investigation and conclusions.

STAGE 4: Corrective Action, Follow-up and Closure

The auditee takes corrective action to eradicate the root causes of nonconformities found during the audit. The audit team and, sometime, the clients who have requested the audit, should be kept informed about the implementation of the corrective action, which must be conducted promptly and effectively. Built upon the analysis of the causes of the problems, it should prevent reoccurrence of the same discrepancy or the emergence of a new one of the same nature and should accomplish the following objectives (Russell, 2000b):

- Identify the problem and isolate the important triggering event
- Identify the underlying cause of the problem
- Identify the potential of the problem to occur in other areas
- Find a solution for the causes and develop a plan for solving the problem
- Identify the manager's responsibility for the corrective action
- Document the corrective action plan
- Establish timelines and provide a schedule of the dates when action is to be initiated and completed

Depending on the complexity of the action plan, the auditor can choose to return to the work area, observe the new process, and ensure that proposed action plan has been implemented.

2.2.3 Quality audit improvement

Most quality audits conducted today are compliance audits in which auditors check to see if activities are being done by the book and are instructed to verify the implementation of the prescribed procedures (Arter, 2000d; Gunter, 1998). Thus, according to a 1993 survey of 750 auditors in the UK, the majority of them believed that assessing compliance with ISO 9001 was straight-forwards – the auditor simply had to look for evidence of a documented system (Williamson & Rogerson, 1996). However, the auditees expressed dissatisfaction with the audit's results. For example, they observed that auditors were continuing to audit in the same manner, using the same checklists, often asking for exactly the same information from the same people in every audit (Regel, 2000). The observed shortcomings of this type of compliance audit are

- The compliance audit does not test the underlying system's ability to achieve the organization's objectives. The auditor assumes that the rules are good and leaves such analysis to others to do during the annual management review or as part of the corrective action response to an unsatisfactory condition. Therefore, innovation is discouraged (Arter, 2000b).
- The problems reported in quality audits have a recurring pattern. That is, the same problems are found, reported and corrected in one audit after another, but they still continue to occur. This shortcoming results from the failure to identify the system's failure and to eliminate the root cause of the failure to prevent the reoccurrence of the problems (Russell & Regel, 1996).

- An entire compliance-based audit leads to functions that need more investigation being left for an entire year before being audited again (Wharton, 1997).
- The auditor simply verifies the compliance with the agreed-upon standards without assessing the suitability of these standards or the effectiveness of the quality system to meet quality objectives (Karapetrovic, 2001).

In the light of these criticisms, auditors have been searching for the answers to improve quality audits (Hutchins, 2002; Lowe& Huber, 2001; Gordon, 2001; Karapetrovic & Willborn, 2000a &b, 1998; Russell, 2000c, 1999, 1998; Malsbury, 1999; Arter, 1998; Cahill, 1998; Kildahl, 1998, Hunt, 1997; Gardner, 1997; Dew, 1994; Barthelemy & Zairi, 1994). One approach to improving quality is the integration the quality audit with the self-audit. The rationale of this integration is that quality audits foster quality assurance and product conformance to specified requirements, whereas self-audits facilitate continuous improvement (Karapetrovic & Willborn, 2001b & 2002).

2.3 Year 2000 Revision of ISO 9001 Standard

Since its first introduction in 1987, the ISO 900 standard has been well received by a variety of companies or organizations, with the claimed benefits of "lower costs through reduced wastage and quality improvement", and "increased market share through perceived higher quality and/or improved market opportunity" (Dick, 2000). This response suggests that ISO 9001 is not a "prank played by a group of bored Europeans" (Adams, 1996). In order to accommodate the latest developments in quality management, the International Organization for

Standardization (ISO) published the ISO 9001:2000 version of its standard. The ISO 9001:2000 and ISO 9001:1994 standards offer different models for quality management. ISO 9001:1994 defines "quality" according to 20 key elements a company uses to consistently produce products and services for customers, while ISO 9001:2000 depends upon a process model that any effective enterprise can use (Pearch & Kitka, 2000). This model consists of four sections: Management Responsibility, Resource Management, Product Realization, and Measurement, Analysis and Improvement. By connecting the principals of quality management to organizational processes, the 2000 version of ISO 9000 provides a greater orientation towards continual improvement and customer satisfaction, thus widening the scope and the use of the standard (Jayawarna & Pearson, 2001).

Among the eight quality management principals that the new standard is built upon (Liebesman, 2003; Taormina, 2002; Vavra, 2002; Russell, 2002a; Kolka, 2002; Ketola & Roberts, 2001a &b;), the process approach is the most prominent principal since the whole new standard is based on it. Although the process approach is not a new concept (Melan, 1992) with reported extensive usage (Babicz, 2000; Lee & Dale, 1998; Laitinen & Fayad, 1998; Bal, 1998 Eade, 1995), it presents a significant challenge for many standard users (West, 2001). Within the context of ISO 9001:2000, the process approach includes the processes needed for product realization, and the other processes needed for the effective implementation of the quality management system, such as the internal audit process, the management review process, the data analysis process, and the resource management process. All these processes can be managed by using Deming's "PDCA" concept (ISO, 2001). It

has the following benefits when developing, implementing and improving a QMS (Hooper, 2001):

- It is a generic approach applicable to all sectors and all sizes of organizations, while its implementation is straightforward, using defined methodologies such as process management and improvement.
- It directly manages the creation of value horizontally across functional departments, thus reducing quality problems that occur at department boundaries.
- It directly ties process measures of performance to customer needs and supplier performance, thereby focusing process performance on what is important to customers.
- It is a strong model for continual improvement, with gaps between customer requirements and process performance providing an ideal starting place for improvement efforts.
- It directly supports the system approach to management, with improvements involving everyone and every level of the organization.

The proposed method of establishing the process approach includes the following steps (Gryna, 2001):

- Define the current processes by establishing the process mission, goals, scope and major sub-processes.
- Discover customer needs and flowchart the process.

- Establish process measurements in terms of effectiveness, efficiency, and adaptability to help control process performance and determine process capability.
- Analyze process data to identify opportunities for improvement and to determine the cause of process problem
- Design or redesign the process
- Transfer and manage the new process for continuous improvement

For companies currently registered to ISO 9001:1994, December 15, 2003 is the deadline for them to transfer to the 2000 version of the standard. The transition provides the opportunity to (West, 2002b)

- Refocus the quality system by identifying the key processes that will help the organization reach its objectives and concentrate system-improvement activities on those processes.
- Change the system's emphasis from documentation to management of processes to achieve planned results.
- Broaden the focus from providing training to managing competency.

Satisfying the new standard will give the management benefits including increased use of data as a business-management tool, improved customer satisfaction, increased management commitment, more efficient management reviews, and improved customer communications (Liebesman & Morz, 2002). The proposed transition project includes the following steps:

- Identify gaps between where the company stands currently and where it needs to be (Walker, 2001).

- Secure management's commitment to meeting requirements and reviewing the quality system on an ongoing basis (Delpha, 2002a; Mitman, 2001).
- Survey customers to measure the system's performance, followed by corrective action with possible change (Lilly, 2001).
- Prepare a transition plan and determine the project's scope and permissible scope (Delpha, 2002b).
- Form a cross-functional project team to identify and document the existing activities and processes of the system (Shipley, 2002).
- Set goals and objectives and determine what metrics will meaningfully measure status and progress throughout the organization (McAtee, 2001).
- Define the process, establish measures of process performance and compare process performance with customer requirements (Hooper, 2001).
- Rewrite the quality manual, streamline the procedures, and assign the ownership (Wright, 2001).
- Schedule, conduct internal audit, respond to findings and prepare for registration audit (Landon, 2003).

2.4 ISO 9001:2000 and Quality Audit

The 2000 revision of the ISO 9001 standard inevitably has had a huge impact on quality audits. For auditors, gone are the days of ticking off questions on a list and being satisfied when a check is marked in every box (McAtee, 2001). As Russell (2000a) predicted, the conformity-assessment processes will be challenged over the next several years by the need to make the necessary changes for the new ISO 9001:2000 standard's style. Compared to ISO 9001:1994, one notable change in

the new standard is that many elements demanding no document seem too difficult to assess. Since many clauses in the current standard are less descriptive than the clauses in the previous standard, "the traceability between the standard and user of the quality management system is less obvious and may be suspect" (Russell, 2001). Russell (2001) claimed that "the auditor must verify the organization conforms to the intent of the requirements of the standard by determining whether an approach has been established, implemented, maintained and improved". Russell (2002b) also suggested that auditors apply plan-do-check-act (PDCA) principle to audit system control, and the analyze-change-do-prosper (ACDP) principle to audit continuous improvement.

The auditing process approach itself presents another challenge to auditors as well an opportunity to improve the audit approach. Auditing processes, as they flow through the functions of an organization, may prove to be a value added activity (West, 2002a). The major structural change to ISO 9001 is the creation of four super-processes and the requirement to identify, monitor, measure, analyze and improve all QMS processes (Liebesman, 2002). Liebesman (2002) proposed that when auditing a process-based QMS, the auditor should cover the following steps:

- Develop process checklists.
- Interview process implementers, starting with the process owner.
- Obtain objective evidence.
- Identify findings, including opportunities for improvement.
- Document a description of the process and the findings.

2.5 Quality Audits & Self-Assessments

While the audit's objective is to verify compliance with the criteria, self-assessment is aimed at the examination of drivers for continuous improvement by using the criteria as a framework (Karapetrovic & Willborn, 2001b). Therefore, the synergy of these two types of assessments can be used to help organizations achieve the ultimate quality goal by "transiting from an audit-type conformity assessment to diagnostic, improvement-oriented self-assessment" (Conti, 1998). Since the ISO 9001 standard is just the first step on the road to quality, a quality audit is limited to looking for noncompliance and compatibility between the quality system and the prescribed procedures. On the contrary, self-assessment is able to "involve people at all levels and all units in search of improvements" and to "integrate improvement initiatives into regular business planning and operations" (EFQM, 1999). Compatible with the emphasis on continuous improvement under ISO 9001:2000, self-assessment, in fact, is useful to any organization aiming at improving its performance (Conti, 2001). As Karapetrovic (2001c) pointed out, an organization would first use an audit to determine compliance with a standard, and then would progressively add self-assessment features and approaches before eventually incorporating the quality audit into the self-assessment framework.

As illustrated in Table 2.2, the self-assessment process allows an organization to discern clearly its strengths and areas in which improvements can be made, and culminates in planned improvement actions which are monitored for progress (Van der Wiele et al., 2000). Following the defined principles, auditors perform a fact-based assessment of the auditee's quality management system and therefore provide

management with reliable information for improvement. As one of the audit principles, independence is stipulated as auditors independent of the activity being audited are free from bias and conflict of interest (Russell, 2000b). However, because self-assessment is directed toward one's own activities, this principle upheld by quality audits is contravened. Nevertheless, the definition of "independence" in CAN3-Q395-81(CSA, 1981), "freedom from bias and external influences" does not necessarily prohibit auditors from auditing their own areas.

Table 2.2
Comparison of ISO 9000QMS and Self-Assessment Process

ISO 9000 Quality Management System	Self-Assessment Process
▪ Less management involvement ▪ Driven by external pressure (i.e., customer, regulatory body) ▪ Does not need very deep organizational change ▪ Shows only a few short-term performance improvement	▪ Involves managers across the whole organization ▪ Motivated from within the organization ▪ Stimulates a company-wide continuous improvement

There are three self-assessment approaches (Van de Wiele et al., 1996):

- ***Auditor-driven approach***: focuses on the role of auditors and the steps in which the assessment takes place
- ***Management-driven approach***: business management gives more attention to the development plan and the link that is created between the outcomes of the self-assessment process and business-planning process
- ***Employee-driven approach***: focuses on the employees who are involved in the preparation of the assessment report.

The first and third approaches are suitable for companies with many activities going on in relation to employee involvement and participation, quality planning, policy

deployment, customer and supplier involvement, and assessment. The second approach is used by those companies which start self-assessment activities because of the high importance given to internal reassurance.

Van der Wiele et al. (2000) suggested a four-stages Plan-Do-Study-Act self-assessment model. In much more detail, Karapetrovic & Willborn (2002) explained a seven-step methodology for introducing the self-assessment program:

- The purpose and benefits are studied and explained to selected and/or concerned personnel.
- A test project with a suitable process is conducted.
- The process owner should be formally empowered and assisted without undue interference.
- A self-assessment is conducted with changes made to the plan and approach as found necessary by the owner.
- An oral or written report of results is drafted according to the self-assessment plan.
- On the basis of the self-assessment report, prioritized follow-up actions are decided upon and approved by the process owner and management.
- Implemented follow-up actions are continuously reviewed for effectiveness and efficiency.

2.6 Motivation for the Proposed Research

When the above literature review had been completed, the approaching deadline for the ISO 9001:2000 transition requires that research be conducted to explore the possible role of quality audits in this change. One area to be addressed

was how to modify the current audit methodologies to fit the new elements of the standard. Another area of the research had to deal with applying quality audits as a useful management evaluation tool to help the organization previously registered to ISO 9001:1994 to upgrade its system to comply with the ISO 9001:2000 standard. The research includes the following considerations:

- How to apply quality audits to the ISO 9001:2000 standard is an urgent question need to be answered by auditors. Apparently, the current audit methodology, which was built upon an element-based quality system model, is unable to accomplish the task of auditing the new process-based quality system.
- Instead of viewing a quality system as a set of separate quality elements, a quality audit should consider it as a interrelated process network cascading from the top management level to the operator level. This perception implies that when auditing an ISO 9001:2000 process-based quality system, an auditor should follow these process flows as audit trails.
- When helping a company in its transition effort, a quality audit should be combined with self-assessment to create a real-time audit model that will motivate process owners to perform timely checkups and subsequent corrective actions.
- The proposed real-time audit model should be tied with the process approach demanded by the standard. In other words, the real-time audit should spread throughout the whole company at various process levels.

2.7 Objectives for the Proposed Research

The proposed research had the following objectives:

- Review the concept of process management and its implications for the ISO 9001:2000 quality standard. Re-construct the various processes stipulated by the standard to follow the business-operation flow.
- Following the re-construction of a process-based quality system model, propose a process-based quality audit model to accomplish a ISO 9001:2000 quality audit. Develop the methodologies for implementing this audit model and create an audit checklist as guidance for quality auditors
- Incorporate self-assessment into the quality audit to create a perpetual audit model. The explanation of the concept of this model should include its foreseeable benefits. Present the possible application steps for introducing this model to a company involved in the ISO 9001:2000 transition project.
- Utilize the above models in a business setting to help an organization to upgrade to the ISO 9001:2000 quality management system. Create a project plan for implementing the model. Use the project to prove demonstrate the feasibility of these two models.

3.0 PROCESS-BASED QUALITY AUDIT MODEL

3.1 Introduction

The new ISO 9000: 2000 standards promote the adoption of a process approach when developing, implementing and improving a quality management system (ISO: 2001). A "process" is defined as a set of interrelated or interacting activities which transform inputs into outputs. This definition implies that the auditor needs to verify that the processes of the audited quality system have been identified, controlled, monitored and continuously improved. How to do so poses a major challenge for quality auditors who are familiar with the audit approach in the previous ISO 9001:1994 quality audit.

The ISO 9001:1994 standard divides the whole quality management system into 20 quality elements. A quality auditor needs to evaluate the performance of these quality elements to determine if the recommendation for registration could be made. The major downside of this process is that the operational reality of an audited quality management system is ignored. Audited companies commonly lead double lives: one based on the "documented" quality management system, one on the actual operational system. As well, no consideration is given to the relations between these quality elements and the company's objectives. In other words, pressed by its customers, a company seeking only certification could use a quality system which did not fit with its operation. Moreover, when carrying out an ISO 9001:1994 quality audit, all the auditors have to do is to select the applicable elements and start from there. As shown in Figure 3.1, the audit trail starts with the selection of the applicable

elements, relevant documentation, and quality records. Especially during the follow-up audit, auditors need to pay attention to fewer "major" quality system elements, such as Document Control and Internal Audit, as required by their registration organizations, than need to be considered when using the new standard.

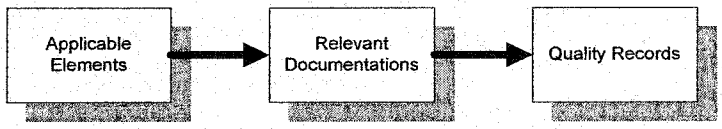

Figure 3.1 Audit Trail of ISO 9001:1994

Obviously, this audit trail is unable to address the need of the new process-based ISO 9001:2000 standard. This chapter proposes a process-based quality audit model conforming to the ISO 9001:2000 standard. This new model pulls together customer requirements, quality policies, quality objectives, applicable processes and sub-processes. The conceptualization of this model is discussed, followed by a description of its benefits and principles. Subsequently, a possible application of this model is described in detail. A checklist which is intended to assist this process-based audit is also presented.

3.2 Conceptualization

With the goal of adding value for an organization and its customers, the ISO 9001:2000 adopts a process approach to enhance customer satisfaction by meeting customer requirements. The answer to how to embody the process approach in a quality audit might lie in the ISO 9001:2000 itself. ISO 9001 provides a quality management system model intended to be applicable to organizations of any nature

and size. Depending on its products and operation, an organization has some leeway to ignore the unsuitable elements of the model.

3.3 Restructured quality management processes

In order to set up a process-based audit model, it is necessary to reorganize the processes stated by ISO 9001 for following the normal business flow and PDCA cycle. The entire processes necessary for the effective implementation of quality management are addressed in Section 4.0 Quality Management System, to 8.0, Measurement, Analysis and Improvement, in the ISO 9001: 2000 standard. The demand from customers or end users justifies the existence of a company. In turn, senior management positions its company according to its strategy deployment. To some extent, strategy deployment is a very interactive process because not only do customers have a key impact on the company, but the company has to choose the appropriate customer group depending on the company's production capability and capacity. Afterwards, in the planning stage, management creates a plan for the product- and service-provision process and the quality management process. The Do stage of the PDCA cycle includes the resource-procurement process and the product- and service-provision process. Resources are purchased from suppliers to carry out the plan. Here, "resource" not only refers to the traditional notion of "personnel, equipment, material, method, environment" but also includes the properties obtained from customers, for instance, customer-provided material, drawings, and testing fixtures. Subsequently, the products are manufactured or the services are delivered as planned. Production or service quality is incessantly monitored and measured during the Check stage. Data gathered from monitoring and measurement are analyzed and

fed into the following improvement process, or Action stage, during which, action plans are proposed, implemented and verified.

As illustrated above, the ISO 9001:2000 quality management system model consist of six major processes:

- Strategic Deployment Process
- System Planning Process
- Resource Provision Process
- Implementation Process
- Monitoring and Measurement Process
- Improvement Process

Each of these processes consists of several related sub-processes. The interrelations between these processes can be depicted as in Figure 3.2.

3.3.1 Strategic Deployment Process

The organization begins by determining and reviewing the customer requirements by using the customer-related process (Clause 7.2). Next the senior management of the organization deploys its business strategy, including its vision and mission statement, designed to meet customer and applicable regulatory requirements. Unfortunately, the current ISO 9001 standard does not address this essential part of business processes.

3.3.2 System Planning Process

Within the framework of the overall planning process, the organization lays out its quality management system (Clause 5.4) with output such as a quality policy and quality objectives. The necessary processes of the quality management system are

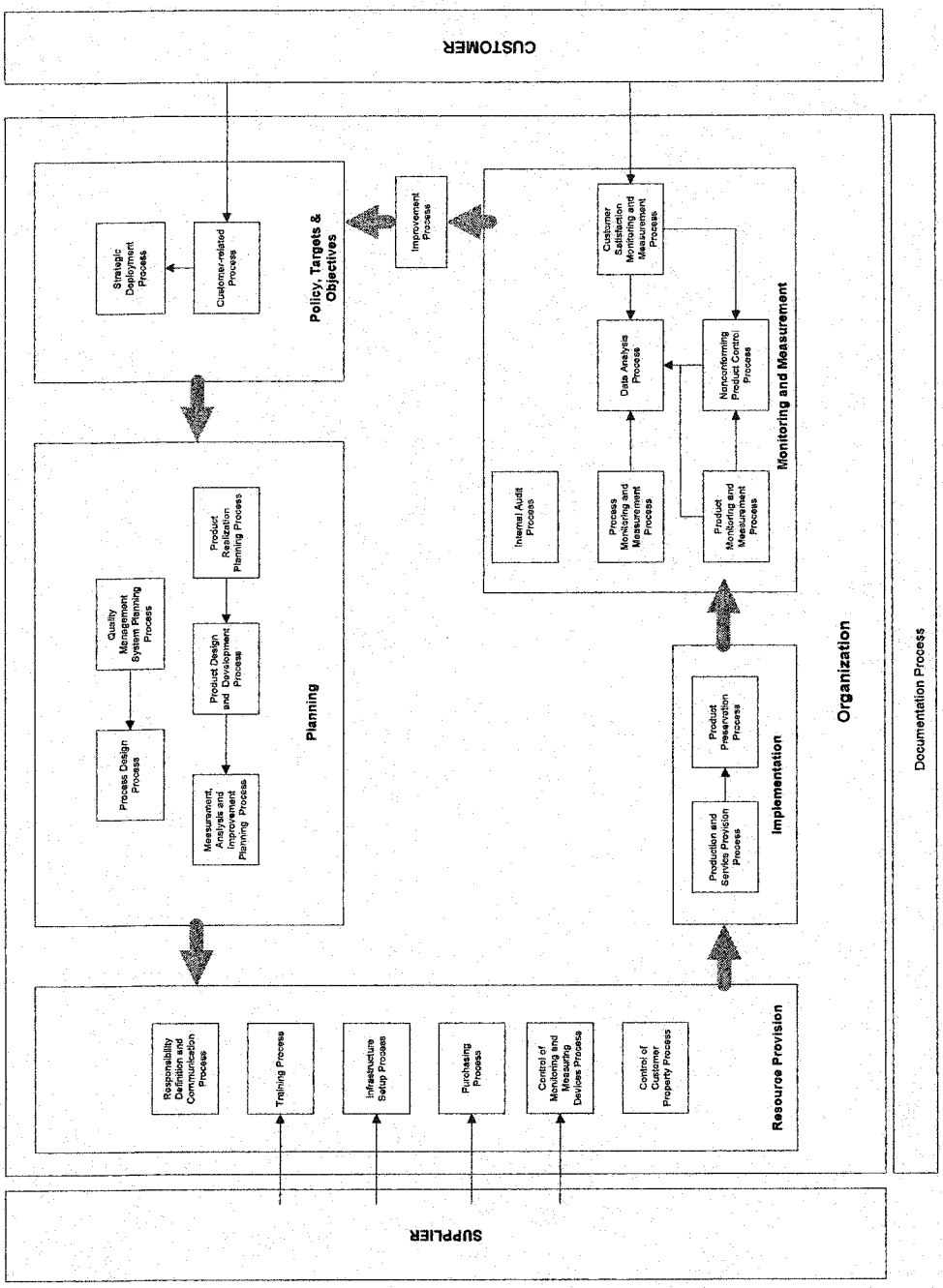

Figure 3.2 Restructured View of Quality Management System Processes

decided upon based on the organization's policies, objectives and operation. Some processes, such as the purchasing process (7.4), are not applicable to a manufacturer which has its materials provided by a customer. However, a company has to read carefully about Section 1.2, Application of ISO 9001:2000, before any exclusion be made. Production realization planning (7.1) is carried out to determine any necessary manufacturing or servicing processes. Product or service design and development (7.1) is the process of converting customer requirements into tangible products or intangible services by means of design. As well, the processes relevant to measurement, analysis and improvement (8.1) are planned at this stage to ensure that the product's or service's characteristic can be measured.

3.3.3 Resource Provision Process

Resources can be categorized into two groups: human resources and physical resources. With respect to human resources, the organization needs to define and communicate responsibility and authority (5.5). Training (6.2) is provided to make sure that involved personnel acquire the necessary competence. The physical resources include an infrastructure (6.3), which is set up, and a working environment (6.4), which is managed to achieve product or service conformity. Material is procured through the purchasing process (7.4) from suppliers. Monitoring and measuring devices needed to provide evidence of the product's conformity to requirements are acquired and controlled (7.6). In the last stage of the resource provision processes, any customer property under the

organization's control or being used by the organization is identified, verified, protected and safeguarded (7.5.4).

3.3.4 Implementation Process

With all the information and resources as input, the organization begins to implement the production- and service-provision process (7.5) as planned. In a manufacturing setting, work orders are completed by sequential flow in the production process. The production process follows the specifications and procedures obtained through the design process. Workers use work instructions to direct their individual operations. Preservation measures are taken to keep the final product intact during internal processing and delivery (7.5.5).

3.3.5 Monitoring and Measurement Process

The product monitoring and measurement (8.2.4) process is conducted to verify that product requirements have been met. When a nonconforming product is found during internal processing or from the monitoring of customer satisfaction (8.2.1), it is identified and controlled (8.3). As a measure of monitoring the performance of the quality management system per se, an internal audit is regularly conducted. All the data from these monitoring and measurement activities are collected and analyzed, in many cases, by means of statistical techniques.

3.3.6 Improvement Process

The outcome of the analyses in the previous monitoring and measurement process are used as input for the improvement process (8.5).Corrective actions are planned and taken to address the nonconformities found during the monitoring

and measurement stage. The results of these actions are assessed to determine their effectiveness. If the planned results have not been achieved, the responsible unit reappraises the situation and proposes a more suitable corrective measure. As well, by identifying the trends in the monitored processes, preventive action is implemented to avoid the occurrence of foreseeable nonconformity. The correlation between the instable and stable processes creates another opportunity for preventive actions used to prevent further problems.

3.4 Process-Based Quality Audit Model

Before discussing the process-based audit model, this section will review how an organization deploys its quality management system and related processes. This review identifies the principle on which the process-based audit model is built.

The two system-deployment methodologies available to senior management are the Department-Initiated and Process-Initiated methods.

3.4.1 Two Types of System Deployment Methodologies

The department-initiated system deployment approach is represented by Figure 3.3. Under the guidance of quality policies, quality objectives are established and various departments are assigned the task of achieving these goals. Each department tries to achieve the determined quality objectives, which sometimes are the same and sometimes are different across the departments. Each individual department has to design a variety of processes to realize its assigned quality objectives. As well, each process is broken down into sub-processes as indicated in the Figure 3.3. For instance, the marketing department has a market-

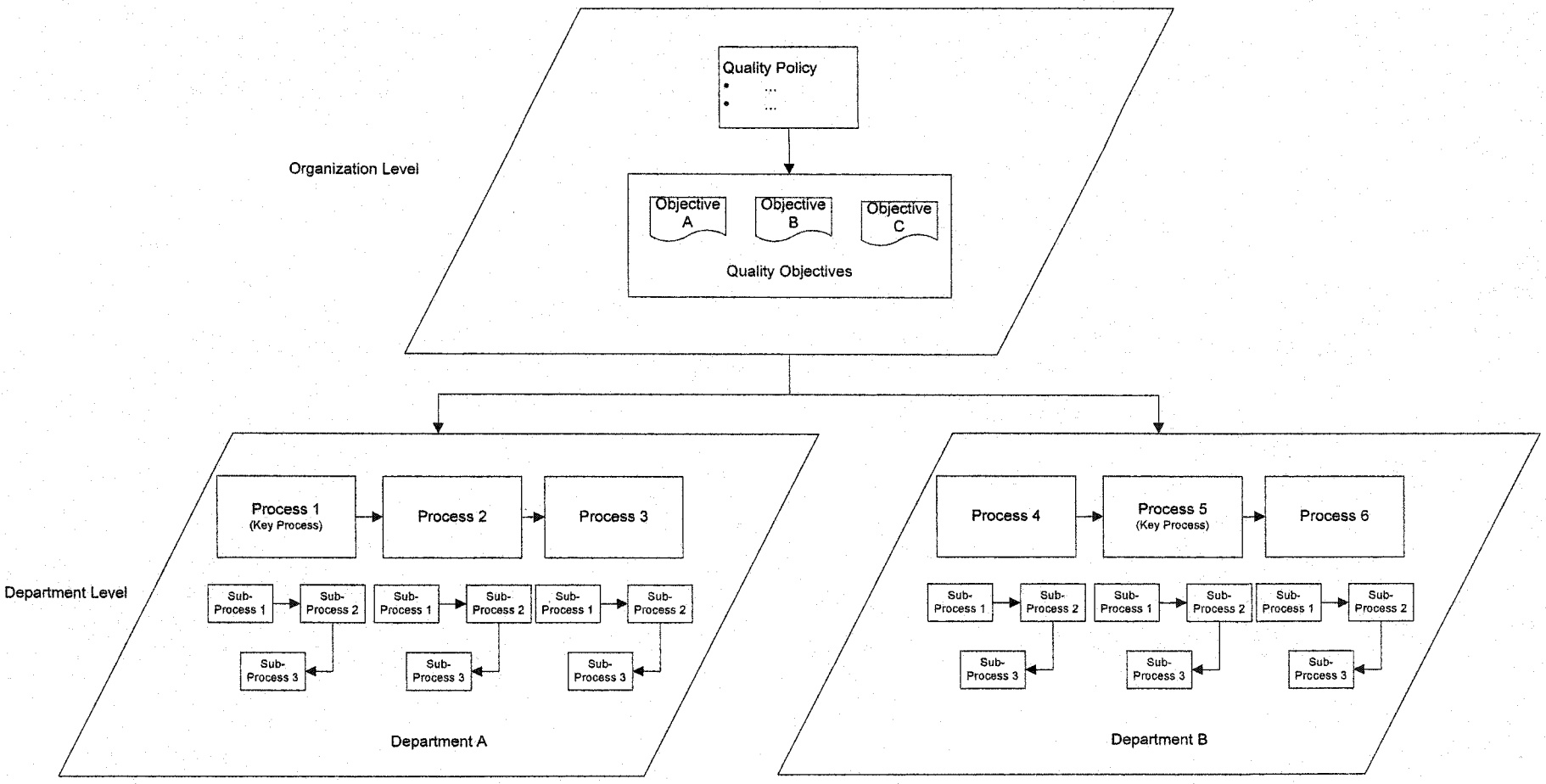

Figure 3.3 Process-Initiated Quality Management System Deployment

forecasting process, customer-ordering process, and external-document-control process. If one of the company's quality objectives is to shorten its order-fulfillment time span, the customer-ordering process and external-document-control process will be deemed as key processes because the company must reduce the time spent on processing and reviewing customer orders as well as transferring updated customer-specification documents to the design department. Since departments are well established at the beginning stage of the department-initiated system-deployment process, their roles and responsibilities are easily and clearly defined. Moreover, as each department owns various processes, the departments have an additional incentive to control and improve them.

On the other hand, an organization also could opt to use the process-initiated approach to deploy its quality management system (Figure 3.4). Instead of defining the system by departments, the system planning identifies a number of major processes at the organization level. Different departments own a portion of each major process, which will break up into sub-processes. For example, consider the customer-order-fulfillment process. The marketing department is responsible for obtaining an order. In sequence, the production, R&D, and quality departments are involved in determining if the company has the capability to satisfy the customer requirements as per the order. Again, the defined process serves the needs of predetermined quality policies and objectives. The most obvious advantage of using this methodology is that the communication and linkage within the process are secured because this method uses the process as the

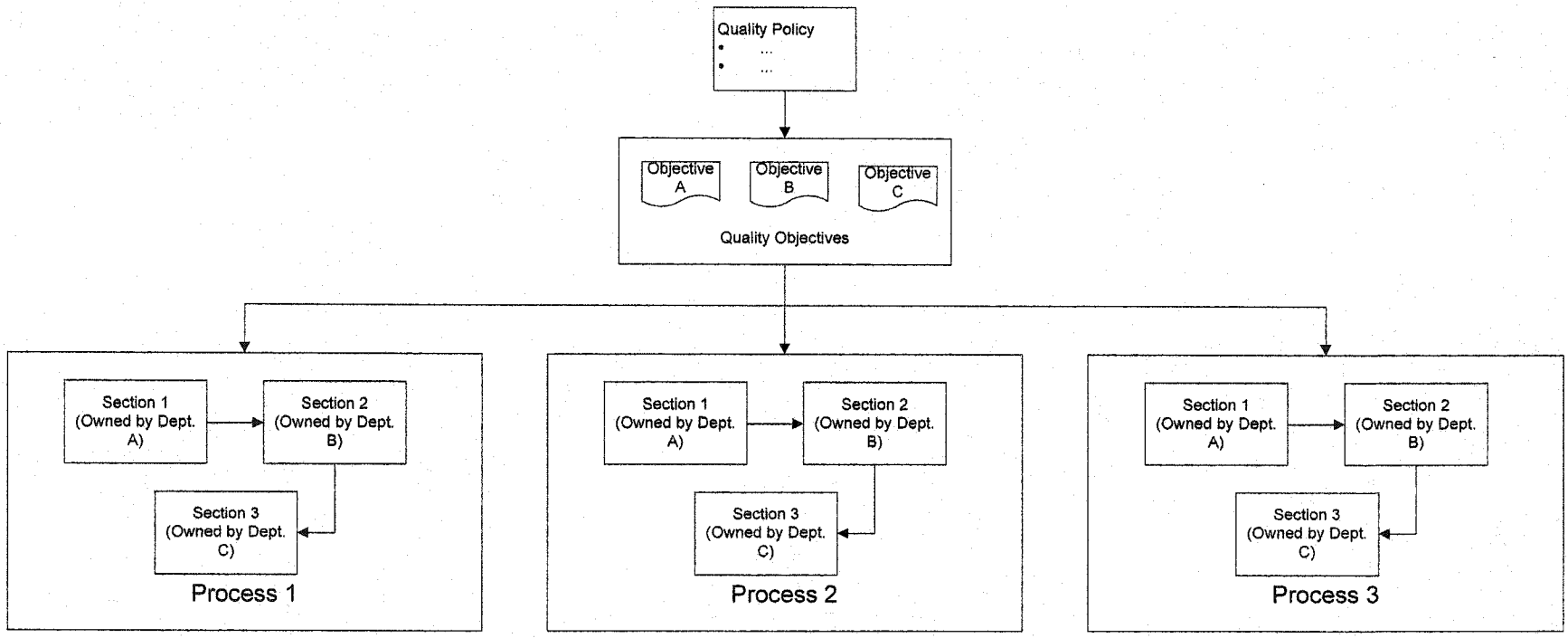

Figure 3.4 Department-Initiated Quality Management System Deployment

basic element of the system. In other words, the organization assures the continuity of the process flow.

3.4.2 Auditing Elements

No matter what system deployment approach is taken, the auditor expects to find out the same following elements:

- *Departmental Quality Objective*

  It may develop out of the organization's quality objectives, or sometimes, it is even a part of the organization's quality objectives. Conformity and correlation between these two objectives are essential because, ultimately, the organization's overall quality objective is to be achieved with the planned time frame.

- *Process*

  Every department owns some processes that justify its existence. In many cases, as mentioned before, these processes are parts of the major processes which flow through several departments. Departmental quality objectives involve the key processes. A "key process" is a process that is decisive in terms of achieving quality objectives. As indicated before, different objectives lead to various key processes. Usually resources, time, and personnel are prioritized to key processes. In other words, the key processes are a company's focus in the attempt to accomplish substantial improvement within a given period.

- *Sub-Process*

A process is divided into sub-processes owned by various units within a department. For instance, the product-monitoring and measurement process is broken down into unfinished and finished product-monitoring and measurement sub-processes, which are owned by in-process quality-assurance units and final-quality-assurance units, respectively.

- *Activity*

  A sub-process consists of several activities owned by individuals in a department. An activity is the basic element from the process-management perspective and is operational and actionable. In the finished-product monitoring and measurement process, obtaining product-quality documents is the first activity, followed by determining the inspection sampling plan. In some cases, each individual is responsible for one activity while in other cases each individual owns several activities. An individual's amount of ownership depends on the complexity and scope of the process and sub-processes.

3.4.3 Two levels of Quality Audits

Based on the above analysis, a process-based audit model is comprised of two levels of audit as shown in Figure 3.5.

3.4.3.1 Top Management Audit

The subject of this audit is senior management since they are responsible for planning the whole management system. This audit begins by focusing on how

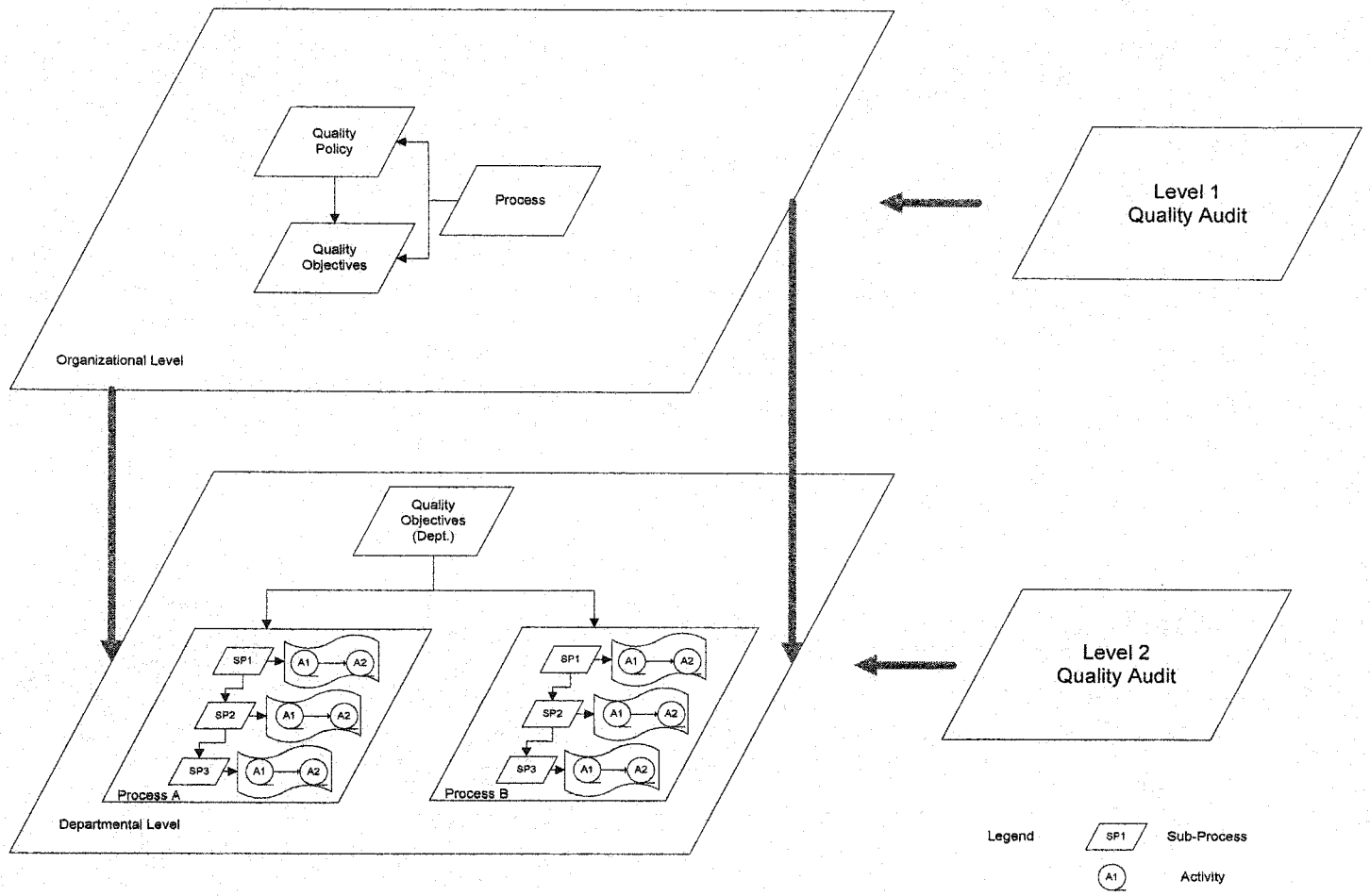

Figure 3.5 Process-Based Quality Audit Model

The senior management determines the company's long-term strategy. Using quality policy as a framework, the auditors put the suitable quality objectives in a quantifiable form. In this sense, a quality objective is like an achievable embodiment of quality policy. The correlation between the quality policies and quality objectives is another focus during the audit. Because the quality objectives determine the key processes, the auditor should use this audit output to guide the following department audit. Bearing in mind that this kind of quality deployment itself is a process, the auditor needs to use the process audit methodologies described hereafter to assess its performance. Furthermore, other processes owned by senior management are also audited during this stage. These processes include the management review process, internal audit process, responsibility definition and communication process etc.

3.4.3.2 Departmental Audit

This audit is used to evaluate the performance of individual departments. The quality elements are guided by departmental quality objectives. The alignment of departmental and corporate quality objectives is one of the issues that the auditor should initially pay attention to. As well, departmental quality objectives designate the key processes within a unit. During the next stage of the audit, the auditor begins by examining the performance of the processes which the department is accountable for. By applying process-management methodologies, the subsequent process essentials become the key factors in a department's success.

- Process Boundary/Input/Output/Ownership

Process boundary, input, output and ownership are the effective indicators of a successful process identification according to the ISO 9001 standard. Only if the process boundary is clearly determined, can the so-called process control take place. This determination is initiated by defining the process's input and output in a suitable form. Senior management then assigns the ownership of the process to the responsible staff. Auditors need to gather information about the above elements even though relevant documentation is no longer considered as mandatory. The decline in documentation requirements is one of major amendments in the 2000 revision of the ISO 9001 standard. The auditor can interview the departmental head to acquire the necessary information. However, in most cases, the process input and output are available in a tangible form including customer orders, product specifications, and work orders. The auditor should take note of the previous and subsequent processes as well as their process inputs and outputs in order to assure the audit's continuity.

- Sub-processes and their sequences

As noted before, sub-processes are linked together to form a whole process. During the second step of a department audit, the auditor needs to verify that the sub-processes are correctly recognized and established. The information flows between the sub-processes also have to be evaluated to determine a process's effectiveness. As well, the auditor needs to identify the owner(s) of the sub-processes. For the following audit, they will provide further information about the activities in each sub-process. Many

organizations opt to use a flowchart to document a process. The auditor has to use his or her discretion to determine how to obtain the evidence to verify the preceding information.

- Process Control Method

After the process is defined and established, the auditee determines how the process will be controlled. This determination explains the "how" aspect of process control. For example, the methods of reviewing purchase orders and selecting appropriate sub-contractor s are indispensable in a procurement process. These methods usually evolve from the practices that have been proven to be the most effective. Typically, a specific procedure and work instructions are used to define the control methods. Training may be used to as an alternative to not having any documentation. If documentation is used as the form of detailing the control method, the auditor has to vet the associated document-control process. However, if training is employed as the alternative, the training process has to be verified to see if the sufficient training has been provided to the employees involved to enable them to handle their jobs.

- Process Performance Metrics

As the old saying goes, only something that can be monitored can be controlled. Metrics are the indicators of process performance. After the metrics are determined, the relevant goal and timeframe for achieving it are established. Especially for key processes, performance metrics are highly related to the quality objective because achieving the goal depends

these projects achieving their own objectives. For example, daily or weekly produced units are the performance metric for the production process in order to determine the production process is achieving its full potential.

- Process Performance Measurement and Improvement

Performance measurement is conducted to obtain the data for the process metrics. Performance measurement methodologies need to be studied to ensure their conformity to the definition of the metric goals. If the data indicate the planned goal has been achieved within the given time frame, the process will be reevaluated to either establish a higher performance goal or to select a new performance metric in order to continuously improve the process. On the contrary, if the department or unit fails to achieve its performance goal, the root cause of the failure needs to be determined, followed by the appropriate corrective and/or preventive action to eradicate the failure's cause. However, sometimes process measurement may not be performed by the members of each department, and instead the quality-assurance department which specializes in product and process measurement provides the necessary data. If so, as well as following the information flow to other departments, the auditor should determine if the data are being conveyed in an accurate and timely manner.

By applying this two-level process-based quality model, the auditor is able to assess the performance of the quality management system throughout the embedded flow of the system's deployment. The restructured quality management

processes depicted in Section 3.2.1should be used a guideline, especially during the audit planning. As well, the auditor also could also use this audit model to audit at the level of activities.

3.5 Benefits

The benefits of using this process-based quality audit model are

- It addresses the puzzling question that auditors ask when they face a ISO 9001:2000 quality audit: "How are we supposed to do it?" In general, this model incorporates process management principles into the quality audit. No better solution exists for conducting a audit of a quality management system which uses the process approach advocated by the ISO 9001:2000 standard.
- This model gives the auditee a value-added audit service by taking the auditee's operation into account. Contrary to the previous rigid "by element" ISO 9001:1994 audit approach, this model follows the operational quality system flow, from quality policy, quality objectives, processes, sub-processes to activities. Auditees do not have to separate their quality system from their daily operation. Instead, they have the opportunity to include the quality system element as an integral part of their daily operation. Furthermore, this model allows auditors to perform a dynamic and in-depth examination at the activity level rather than just sorting through some superficial facts. For this reason, this model puts some pressure on the auditees because they have to make an effort to establish a meaningful quality

system. However, this kind of system will ultimately benefit their organization.

- This model fosters continuous improvement required by the 2000 version of the ISO 9001 standard. Auditors look for the evidence of process improvement when evaluating the process performance metrics and measurement. Therefore, the audited organization or department needs to provide proof for how the process performance has been improved, even if the performance goal has not been achieved. Thus, this model requires organization to involve themselves in a never-ending pursuit to improve their processes.
- This model is generic in the sense that it can be used not only during an external audit for certification purposes but also during an internal audit for improvement purposes. To some extent, an internal auditor might gain more benefits from it because this model can require more time than an external certifier can spend, as well as a high degree of familiarity with the auditee's operation if a full-fledge system audit is desired. If the internal auditor wants to utilize this model for a system audit, he or she should not plan to complete the whole internal audit planned during a few consecutive days. Rather, the audit should be undertaken at different times because otherwise, it may disturb to the normal operations of the organization or department.

3.6 Application

The purpose of this section is to explain how to apply this process-based model in a third-party ISO 9001:2000 certification audit. The explanation covers the whole audit process through audit planning, implementation, reporting to follow-up. A comprehensive and generic audit checklist is included in this chapter and is ready to be used with minor adaptations whenever necessary. Instead of following the traditional audit approach, which primarily includes a desk-top audit and on-site audit, a two-stage audit approach is used, corresponding to the two-levels of quality system deployment.

3.6.1 1st Stage Audit

The audit conducted at this stage is designed to serve two needs: to perform an audit of senior management and to work out an audit plan for the 2nd stage audit. At first, in order to gain an initial understanding of the audited organization, the auditor should review the quality policy, quality manuals, and other applicable documents relating to the processes owned by senior management. The auditor may assess but not limited to the following information:

- Does the quality manual address the standard's requirement?
- Does the auditee have a clear and compatible organizational structure and assignment of responsibilities to realize the auditee's quality plan?
- Does the documented quality policy satisfy the principal required by the standard?
- Do the processes owned by senior management have sufficient

documentation, as required by the standard? For instance, does senior management have adequate documentation for an internal audit?

If no discrepancy is found, the auditor should proceed to audit the senior management. This type of audit could take various forms including an initial on-site audit, a telephone interview, or document scrutiny. Table 3.1 details what information should be gathered at this phrase. Since the quality policy has been evaluated beforehand, the quality objective is prioritized as the first audit subject. As illustrated in Table 3.1, the quality system's goal, current performance, involved processes, and monitoring information are obtained. In terms of objective information, the auditor looks for the method, frequency and responsible department or personnel as well as the relevant records used to gauge system performance. This step is followed by the assessment of quality planning activities for achieving established quality objectives. The auditor focus on the detail of the quality plan, including its time span, responsible department, relevant processes and documentation, and current status. The major output of the 1st stage audit is process identification, which lays the foundation for the next stage of the audit. Based on the information obtained, the auditor develops the audit plan for the 2nd stage on-site audit. As discussed previously in this chapter, special attention should be given to the key processes that are instrumental in achieving the quality objectives and plans. This focus will help the auditor to decide how to appropriately assign the audit's resource to the relevant department and processes. Finally, the auditor allocates the identified quality processes to each department while the applicable standard elements are noted.

QUALITY OBJECTIVE								AUDIT FINDING
ITEM	TARGET	CURRENT PERFORMANCE	RELEVANT PROCESS	MONITORING				
				METHOD	FREQ.	RECORDS	RESPONSIBILITY AUTHORITY	
REVIEW DATE: RESULTS:				PARTCIPANT:				
QUALITY PLANNING								
PLAN	DATE		RELEVANT DEPT.	PLANED CONTENT	AFFECTED PROCESSES	RELEVANT DOCUMENTS	IMPLEMENTATION	
	START	FINISH						
RESPONSIBILITY & AUTHORITY								
RESOURCE PROVISION								
PROCESS								
PROCESS	PROCESS OWNER		RELEVANT DOCUMENT					

Table 3.1 1st Stage Audit Checklist

3.6.2 2nd Stage Audit

The audit is now expanded to include every involved department. As planned, the auditor evaluates the performance of applicable processes as per the standard. Prior to the audit of the processes, the auditor needs to acquire information about the departmental quality objectives. The same approach used in auditing the overriding quality objectives in the 1st stage could be applied here. Key processes are identified, and audit resources are prioritized for them in order to allow for an in-depth assessment. For auditing individual processes, which is the major task of the whole quality audit, the audit checklist shown in Table 3.2 could be used to assist the audit process. Initially, the auditor determines the process inputs and outputs. The interacting departments or functions which deliver the inputs or receive the outputs should also be noted to ensure that the continuity of the process is audited when the auditors move on to these departments. As well, inputs and outputs are verified for their compliance with the relevant requirements. As the audit turns to the sub-processes and activities, their owners are interviewed to obtain the information about their performance to supplement the evidence obtained from reviewing the quality record. During this stage of the audit, the first thing for an auditor to do is to determine if the sequence of these sub-processes or activities is correct. When applicable, the auditor observes the practices to ascertain that they match what is prescribed in relevant documents. The difficult part is that, as not many documents are required by the new standard, auditors may often find themselves with no procedure or

PROCESS:	DEPARTMENT/FUNCTION:	DATE:	AUDIT FINDING

INPUT	REQUIREMENT	DOCUMENTS	RECORDS	RELEVANT PROCESS	ISO 9000 REQUIREMENTS

OUTPUT	REQUIREMENT	DOCUMENTS	RECORDS	RELEVANT PROCESS	ISO 9000 REQUIREMENTS

SUB-PROCESS	OWNERS	METHODS	DOCUMENTS	RECORDS	ISO 9000 REQUIREMENTS

ACTIVITIES	OWNERS	METHODS	DOCUMENTS	RECORDS	ISO 9000 REQUIREMENTS

PERFORMANCE MEASUREMENT

MEASURES	TARGET	CURRENT PERFORMANCE	RELEVANT ACTIVITIES	MONITORING			
				METHODS	FREQ.	RECORDS	RESPONSIBILITY AUTHORITY

CONTINUOUS IMPROVEMENT

Table 3.2 2nd Stage Audit Checklist

work instructions to refer to. Therefore, the auditor might have difficulty determining whether the methods being used to control a process are effective. In this case, the auditors should use their discretion. The rule of thumb is that as long as the process's outputs meet the process's requirements, and the data obtained from the subsequent process measurement proves that the planned target has been achieved, the control method is sufficient and effective. After this stage has been completed, the information pertaining to how the measurement is carried out is also looked into. The interesting aspect of this activity is to explore how the data from the product and process measurement are processed. Last, the auditor reviews the process-improvement activities by answering the following questions:

- How are the product and process data analyzed in order to provide input for process improvement?
- When any corrective or preventive action is initiated, how is it implemented and verified for its effectiveness?

The audit checklist attached at the end of this chapter was developed for an electronic-component manufacturer from whom we used process-based audit model to help build a ISO 9001:2000 quality system. For the audit's status, the checklist list uses CP (complied with standard requirements), MA (major nonconformity found), MI (minor nonconformity found), NA (this element is not applicable to the auditee) and IP (currently in progress) to categorize the audit findings. IP applies to the scenario in which the company does not conform to a standard element, but is in the progress of fulfilling the development improvement

plan in order to satisfy the standard's requirement in the foreseeable future. The use of IP acknowledges the fact that an organization is always in a dynamic state and should not be penalized for its improvement effort.

3.7 Chapter Summary

In this chapter, a process-based quality audit model intended to be applied to the ISO 9001:2000 quality audit was proposed. The chapter began with a discussion of the inherent inadequacy of the traditional audit model, which was established against the previous ISO 9001:1994 standard. To set the groundwork for this model, the processes involved in the ISO 9001:2000 standard were regrouped into six major processes following an organization's normal business flow. From a process management standpoint, the whole quality system is viewed as the entire set of processes, sub-processes and activities which are conducted at different hierarchical levels. The model consists of a two-phase audit: a top management audit and a department audit. The underlying focus of these two audits is the deployment, implementation, measurement and improvement of quality objectives and process performance targets established by senior management according to customer expectations. With this focus, the audit adds value to the auditee's quality system by tracing instead of segregating the main elements of the inherent operation flow.

However, in terms of helping the company transfer its quality system from ISO 9001:1994 to ISO 9001:2000, this process-based audit model apparently is inadequate. Theoretically, this task demands the participation of the whole workforce in a company. In another words, as well as having external or internal

auditors periodically assess the system's status, the process owners should take the initiative of evaluating their own processes. The following chapter presents such a self-audit model with the aim of helping companies implement the ISO 9001:2000 quality system.

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
5.4.1	**Quality Objective**							
	Have department managers ensured the quality objectives have been established within the department? Have the quality objectives been documented?							
	Are the quality objectives consistent with quality policy, company's overall business strategies and objectives?							
	Are the quality objectives sufficient to meet the requirements set up by external and internal customers in terms of product and process outputs?							
	Are the quality objectives defined in quantified forms?							
	How are the relevant personnel notified of quality objectives?							
	Are the quality objective measured continuously by management?							
	What follow-up actions have been taken after the quality objectives were measured?							
	Have the responsibilities and authorities for establishing, implementing, monitoring, reviewing and revising the quality objectives been defined?							
5.4.2	**Quality Management Planning**							
	What quality plan has been addressed by management in order to achieve quality objectives?							
	Which processes have been identified to be controlled or improved in the quality plan?							
	Has the relevant resource been identified and provided in order to implement the quality plan?							
	Has the quality plan been monitored for its achievement status?							
5.5.1	**Responsibilities and authorities**							
	How have the responsibilities and authorities within the department been defined and communicated throughout the department?							
	Is the definition of those responsibilities and authorities valid in the current operation?							
	Have the responsibilities and authorities for establishing, implementing, monitoring, reviewing and revising the plan been defined?							
	Who has the responsibility and authority to define and communicate the responsibilities and authorities?							
	If there is need to change the responsibilities and authorities, how would the change be made?							
5.5.3	**Internal Communication**							
	Has the information relevant to the effectiveness of QMS been identified? If so, what is this information?							
	\What kind of communication channels or mechanisms have been employed to facilitate communication?							

Table 3.3 Process-Based Quality Audit Checklist

4.0 A Perpetual auditing Model for QMS Upgrade to ISO 9001: 2000

4.1 Introduction

One of the major changes in the year 2000 revision of the ISO 9001 standard was that a process-based model replaced the previous element-based model. ISO 9001:2000 promotes the adoption of a process approach for developing, implementing and improving a quality system (ISO, 2001). However, the conventional quality audit approach, which is based on a element-based quality management system model, fails to address this shift. Very often, quality auditors developed the audit plan by selecting the applicable elements for each department or function after reviewing the documents. Even worse, during the surveillance audit, many registrars confined their audit to a subset of "important" system elements, i.e., Section 4.3, Contract review, and Section, 4.5 Document and data control. The most deficient part of his approach was that the interaction between elements was neglected and, hence, the auditors could not provide an complete picture of the quality system. Many nonconformances with the standard originated from the inconsistencies between departments within one element, or between elements within one system. For this reason, the quality audit was called "auditing for maintenance of registration" (Beeler, 1999) or a "routine check". The traditional audit approach should be modified to incorporate the process approach. In particular, more attention should be given to the interaction among processes. The quality audit has been criticized by many quality professionals for its "compliance audit" nature. That is, auditors go about their auditing assignment

by verifying the operation against a number of quality documents including the quality manual, quality procedures, and work instructions . The new ISO 9001: 2000 standard decreases the documentation requirement, which used to be under heavy attack by standard users. Technically, any organization needs only six mandatory documents to satisfy the standard's requirements. In the "good old days", the auditors could simply follow the auditee's documents to find many nonconformances and then conclude their audits. In some cases, the auditees realized that the findings on their audit reports were trivial and meaningless. Another cruel fact is that many organizations live different lives on paper and in reality. Finally, many auditees were paying an enormous amount of annual audit fees to the registrar only for the sake of maintaining their certifications. Fortunately (or unfortunately?), things have changed. As many less prescriptive or non-prescriptive clauses are presented in the new standard, the auditor "must seek conformance and provide traceability to determine the existence of a process, how it was planned and implemented, its outcomes and whether management determines ongoing effectiveness" (Russell, 2001).

Depending on the size and complexity of the auditee, auditors normally take two or three days in an initial audit of a mid-sized company. Subsequently, a surveillance audit aiming to verify the maintenance and improvement of a QMS is performed twice a year. Accordingly, the auditee arranges for two internal audits just before the auditor arrives to make sure "everything is O.K." This type of "snap shot" audit can not provide much beneficial information about an organizational operations nor much input for continuous improvement. As Beeler

(1999) pointed out, external audits are too limited in scope, frequency, timing, and expertise to become the driving force behind an effective continuous improvement effort. Continuous improvement has been deeply embedded in many clauses of the ISO 9001:2000 standard's permanent pursuit of QMS. For an effective audit, requirements of time, human resources and specific knowledge are too great for an external audit party to satisfy. Therefore, the process owner should take the initiative to verify that the planned continuous improvement has been carried out.

Another quagmire of the traditional audit is caused by its incoherence. Normally a certain amount of "black-out" period occurs between two audits. During this period, no prompt feedback about system performance is available. This lack of feedback is very dangerous for the company because of the dynamic nature of organizational operations. Many nonconformities in the product or process occur, necessitating the immediate re-evaluation of the quality system. For example, when the previous documentation control system becomes dysfunctional, a company can implement a virtual document library on its intranet to cut the annual huge paper cost, but with a conventional quality audit model, doing so is impossible until the time comes for the next audit. To some extent, corrective and preventive action might alleviate the deficiency caused by the lack of a timely system audit. However, this kind of action is "reactive", not "proactive", in nature, because it starts after the discrepancy in the system becomes evident. For this reason, the ever-changing system operations justify an incessant and timely quality system audit.

In order to maximize the return of a quality audit based on the ISO 9001:2000 QMS standard, a typical quality audit should be integrated with self-assessment. The justification for doing so is that self-assessment by far outperforms an audit in terms of identifying strengths and opportunities for continuous improvement, prevention of problems, and incorporation of assessment results into the strategic and operational business planning (Karapetrovic & Willborn, 2002).

4.2 Self-Audit

Any organization faces change every day from external and internal sources. On one hand, a company develops a new product or changes the performance specification of the current products to accommodate the latest needs of consumers. These changes either require the new product development or engineering changes that involve all the involved departments. On the other hand, a company is forever in pursuit of higher quality products or services at less cost. Stakeholders use the bottom line figures to press the company to provide a maximum investment return. Accordingly, a company has to keep optimizing its functional deployment and business processes to respond to the demands from its stakeholders. Since change is the eternal theme for any organization, from a quality perspective, an organization needs a perpetual audit of the well-being of its quality system by constantly measuring the system performance against the set targets and objectives. Whenever any discrepancy is found, ensuing improvement actions are taken to address the issue.

The emergence of the self-audit has been attributed to the widespread adoption of the business excellence model including MBNQA and EQA.

According to Karapetrovic and Willborn (2002), motivated process owners perform self-audits to provide immediate or on-line feedback on performance. Compared to the quality audit, the self-audit has the ability to increase the quality awareness throughout a company and, hence, to foster continuous improvement. Process owners have the best knowledge of their own processes and therefore are able to provide the best solution to improve the process performance. However, the use of self- audits is limited mainly to the companies who are implementing the Business Excellence Model. Part of the reason for the rare application of the self-audit with ISO 90001 system is that this application requires certain level of system maturity. However, for a company involved in a ISO 9001:2000 transition project, a self-audit is feasible since the majority of its elements were already established in the ISO 9001:1994 model.

The purpose of the perpetual self-audit model is, based on the conventional quality audit approach, to integrate the self-audit into the audit approach so that the company fosters the process approach and continuous improvement efforts. The use of the self-audit model also enables the daily review of system status to obtain the timely feedback and make adjustments to the system whenever appropriate. This chapter focuses on how to utilize the perpetual self-audit model as tool to help a company transfer its previous ISO 9001:1994 system to the new ISO 9001:2003 system.

4.3 Concept of Perpetual Auditing Model

A "process" is defined as a set of interrelated or interacting activities which transform inputs to outputs (ISO 9000, 2000). In other words, one process

can be broken down into several interdependent activities which are the basic elements in the process approach. A "sub-process" refers to a sub-group of activities belonging to one process. Each process and sub-process have owners who are responsible for the performances. Many processes today are very complicated, comprised of various sub-processes and involving several functions of an organization. Similarly, a quality management system consists of a number of interrelated processes. As defined by ISO 9001:2000, the processes needed to establish a quality management system include not only the product realization process, but also a number of management, monitoring and measurement processes, as discussed in Chapter 3. Here, in terms of scope and extent, a system is macro in terms of its scope, while a process, sub-process, or activity involves micro scope of an organization's activities. All these four entities—the whole system, a process, a sub-process, and an activity, share the same three indispensable components; input, output and control.

Based on the above analysis, a perpetual auditing model for conducting four types of audits at different hierarchical levels is proposed (Figure 4.1). The Regular audit could be a traditional external or internal audit conducted periodically by independent, qualified personnel. This "formal" audit is still superior with respect to the objectivity of the evaluation process, the reliability and consistency of audit results, as well as the identification of systematic failure (Karapetrovic & Willborn, 2002). Another major function of the system audit in this model is to verify that the other three types of self-audit were performed

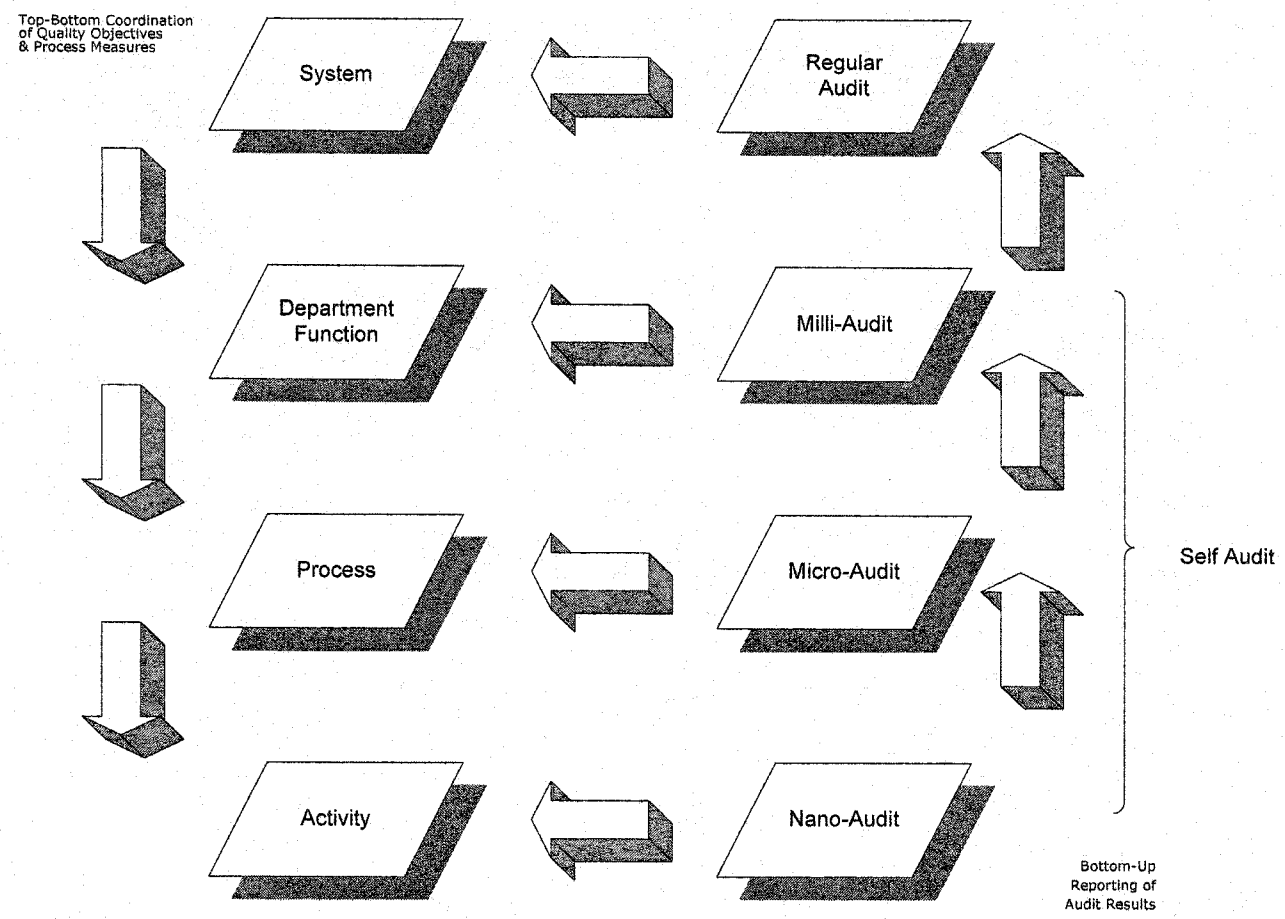

Figure 4.1 A Perpetual Self Audit Model

properly. The three self-audits provide a more detailed evaluation of each process and, consequently, more knowledge for acting on any improvement opportunity. These self-assessments provide an in-depth and dynamic examination of the current status of the company's quality system. Thus, these self-audits provide valuable inputs for continuous improvement. At the process level, the process owner, who is accountable for the functioning and performance of a process, executes the milli-audit comparing process performance with customer requirements, quality objectives, and/or the determined target. In the same way, micro-audit and nano-audit are carried out, respectively, by each unit leader and operator, to evaluate the performance of the sub-processes and activities. Table 4.1 illustrates these audits in terms of audit scope, consumed time, and undertaker.

AUDIT TYPE	AUDIT SCOPE	CONSUMED TIME	UNDERTAKER
Regular audit	Whole System	1/2 -1 Week	Internal/External Auditor
Milli-Audit	One Process	1/2 -1 Day	Process owner
Micro-Audit	One Sub-Process	1/2 -1 Hour	Unit Leader
Nano-Audit	One Activity	5-10 Minutes	Operator

Table 4.1 Comparison of regular audit and self-audits

Because of their relatively brief consumed time, self-audits can be frequently undertaken. The self-auditors have the responsibility of evaluating their own performances. The audit results from an organization's lower level provide important data for audit planning on the upper level. As well, the audit's criteria are sufficiently reviewed to ensure their compliance with the organization's overall quality objectives. More important, the motivated process owner or

operator make sound decisions concerning any corrective and preventive action needed if non-conformance is found during self-audits.

In a nano-audit, the operator conducts a daily check-up to compare his or her performance against an established checklist of performance targets. As indicated by Table 4.1, a nano-audit can take only five to ten minutes depending on the complexity of the audited activities. In order to accomplish such a brief audit, the unit leader or operator must prepare as concise an audit checklist as possible. It can be a summary of the relevant procedures or process maps. The elements to be audited are the critical steps in an activity. They are selected based on its criticality and/or relevance to the quality objectives involved. After completing a nano-audit, the operator will report to the unit leader. If the performance target has not been met, the operator should be empowered to make any appropriate adjustments in his or her performance of the activity in question.

Since a micro-audit takes 30-40 minutes, it should be performed on a weekly basis. Part of the audit task is to measure the status of the sub-processes to ensure that they are under control. The unit leader goes through the entire sub-process flow from the beginning until the end, assessing the sub-processes against a performance matrix. Another part of the audit task is to verify that the nano-audit has been conducted as planned. The unit leader can either verify the nano-audit report or observe the process of the nano-audit. He or she can also address any issue involving the system's efforts to improve the performance of interrelated activities within the same sub-process.

Once a month, the process owners carry out a milli-audit on the processes that they are responsible for. The department audit process proposed in Chapter 2 could be used. A process map is used to guide the identification of the process input/output as well as the measuring of the process performance. The communication among the departments also should be considered. Because no process stands alone in the system, the process owner must report the audit's results to the personnel involved in related processes, especially when a change to the audited process has been planned. Quite often, change to one process will result in a chain reaction that has a huge impact on interrelated processes. A milli-audit may require improvement action to optimize the process's performance. The process owner should close the audit loop by assessing the results of any these process changes.

Figure 4.2 presents a generic framework of self- assessment criteria similar to those of the EFQM Excellent Model. These criteria can be applied when implementing the three self-audits described above. The 'Enablers" are concerned with how the company has achieved the desired quality objectives and targets, while the "Results" embody these efforts in the form of product/service and process quality. Since no point system is assigned to these criteria, organizations are free to prioritize various aspects of them to adapt to the maturity status of their quality systems. The description of each aspect of the Enablers and the Results as well as the audit questions that could be asked about them are presented in Table 4.2

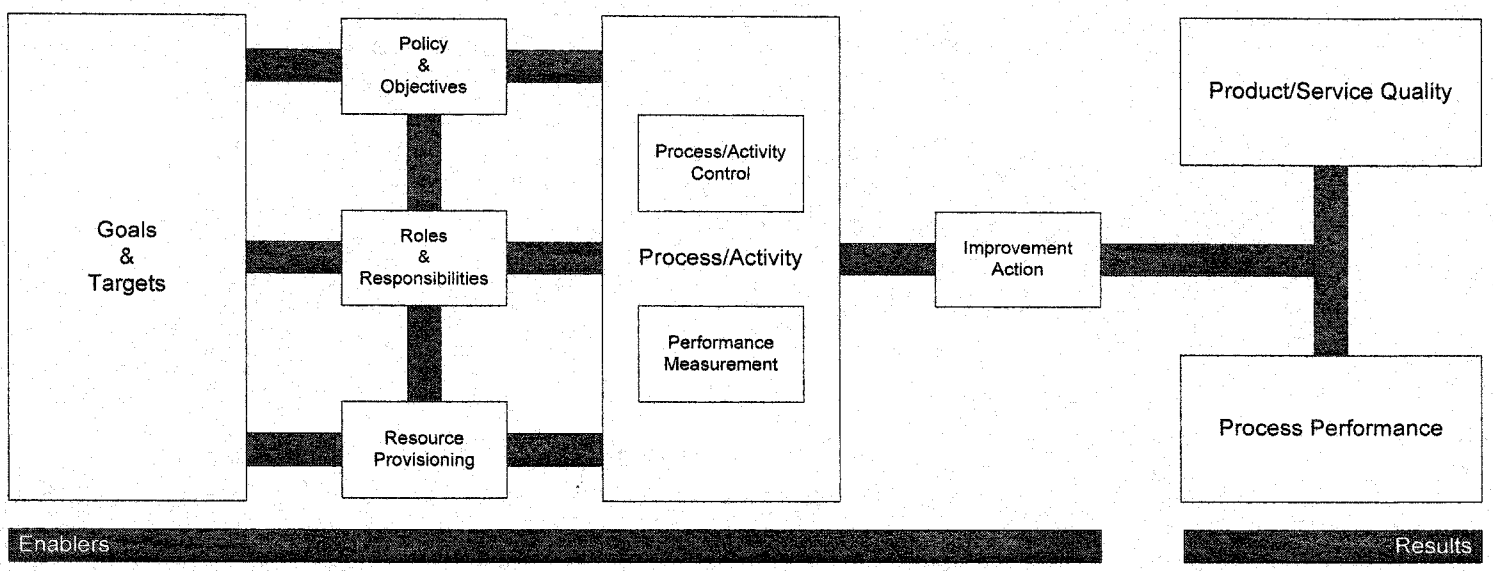

Figure 4.2 Self-Assessments Model Criteria

	ASPECTS	DESCRIPTION	AUDIT QUESTIONS
ENABLERS	**Goals & Targets**	The corporate-level overriding business objectives that the company is striving towards.	How does the executive management value the quality performance of the organization in its business strategy deployment?
	Policies & Objectives	Both define the desired quality results to be achieved through the quality management program.	How are the quality policy and objectives deployed through different hierarchies in the organization in an aligned manner and a meaningful form?
	Roles & Responsibilities	The definitions of the functions of various departments and involved personnel to ensure the implementation of the quality management program.	How are responsibility and authority defined and communicated to enable the system to achieve the defined quality objectives?
	Resource Provisioning	Resources to implement and improve the quality management system.	How are the essential resources, including personnel, infrastructure, material, and information and work environment requirements, identified and made available?
	Process/Activity Control	Approaches to ensure that processes/activities produce desired outputs.	How are the suitable methods established to demonstrate the ability of a process/activity to achieved desired results?
RESULTS	**Performance Measurement**	Evaluation of the process/activity status to in order to fulfill the predetermined quality objectives.	How are the suitable methods established to demonstrate the ability of a process/activity to achieved desired results?
	Improvement Action	Continuously seeks opportunities to improve the process effectiveness and efficiency.	How are the improvements planned, conducted and verified to avoid the occurrence of nonconformity? Should the change management process be taken into account for this aspect?
	Product/Service Quality	As the direct output of process/activity, a product/service is measured to see if the desired results have been achieved.	What is the department/function achieving in relation to its desired targets?
	Process Performance	By using performance indicators, a process/activity is monitored in terms of predetermined performance targets.	What is the performance status of the process/activity?

Table 4.2 Generic Framework of Self- Audit

This perpetual audit model should be conducted in an "informal" way. During a conventional system audit, external auditors may spend a great portion of audit time trying to understand the operation of the audited area. In contrast, self-auditors do not need time to become familiar with their own processes. This advantage of the self-audit enables auditors to use only a small amount of time for a frequent "quick check". In our own experience, a self-auditor can more easily present fact-based audit findings, or get to the "real" system deficiency without the presence of external auditors than a quality auditor can. However, a self-audit violates the widely-accepted principal that an audit should be independent. This violation is justified by the following benefits of a self- audit.

4.4 Benefits

- This approach audits the processes as they flow through the function of an organization and hence "adds value to the quality management system of an organization" (West, 2002). Tying the performance of an individual process or activity to the overall quality system helps to streamline the overall quality effort and focuses on the key process in the attainment of the organization's quality objectives.
- This model allows for the frequent identification of the gaps between process or activity performance and the relevant quality targets and objectives. Therefore, the data obtained through these audits serve as the starting point for a continuous improvement effort which can permeate throughout each level of an organization. The process owner or operator is motivated and empowered to act on any discrepancy whenever one is found.

■ By providing an in-depth and dynamic review of the changing status of an organization, the perpetual audit model overcomes the disadvantages of a mere compliance audit, which is conducted within a brief time span a few times a year. As such, the perpetual audit model enables management to "repeatedly set and strive to meet new and improved objectives" (Karapetrovic & Willborn, 2001).

■ The process owners or operators, the personnel directly involved with the subject of the audit, take the responsibility and authority for their own performance. Since they are the ones most familiar with the relevant operation, they will more easily identify the root cause of any nonconformance found during the audit, and can potentially make sound decisions on the corrective and preventive action needed to improve the process performance. Another advantage of adopting this model is that it overcomes the kind of fear, uncertainty, and perception of coercion, which are evoked by an externally driven or performed audit (Karapetrovic & Willborn, 2002).

■ This model provides a bridge between the ISO 9001:1994 and 2000 standards so that any organization involved in the transition project could easily use the model. As explained in the latter part of this thesis, an organization can use the element-by-element audit approach to gather the data for the transition, and then shift to a process-based audit approach, which effectively validates the performance of ISO 9001:2000 QMS.

4.5 Prerequisites

- A company intending to use this model should have major quality system elements in place and have had some experience with audits. This model is designed to raise the quality system up to a higher level, i.e., to upgrade the quality system to conform to the ISO 9001:2000 quality standard.
- Management commitment is essential for the successful implementation of this model, partly because this type of commitment helps to overcome many unforeseen obstacles during the entire project. Process owners, rather than the quality department or "elite" quality auditors as in the conventional quality audit, take the initiative during a self-audit, which will increase the owner's daily workload. Therefore management must emphasize the audit's long-term benefits to gain the full support of an organization's entire work force. As well, how the results of self-audits are used to improve the quality system is the key success indicator in this model. Therefore, management's support is important because this model requires fundamental change to an organization's policies, procedures and structure as well as its audit system.
- Prior to deploying this model throughout a company, relevant training to equip the future self-auditors with adequate audit knowledge is indispensable. Proposed training topics may include basic audit methodology and the ISO 9001:2000 standard. As part of their training, the future self-auditors could observe or participate in the trial audit to gain hands-on experience.

4.6 Application

Similar to the methodologies of implementing a self-audit, as depicted by Karapetrovic and Willborn (2002), the following seven steps should be taken in establishing a perpetual audit system in an organization. It should be noted that the suggested procedure is appropriate for the case study company. However, it can be tailored to the need of the company that intends to use this model. However, the process owner might become defensive if the results of the self-audit are not according to their expectation.

(1) Initially, a system-wide quality audit should be conducted with the aim of gathering data about the readiness of the quality system. The focus of the system audit should be put on the maturity of the quality system and the capabilities of the internal auditors. If the audit's result is positive, each process's ownership is then clarified and assigned to the appropriate personnel. Process-control methods are determined and demonstrated in suitable formats, i.e., quality manuals, quality procedures, work instructions, and process maps or flowcharts. Resistance to the implementation could be expected at this stage since process owners and operators could view it as extra workload. Awareness training on the purpose and benefits or self-audits is helpful for overcoming this kind of animosity.

(2) Management develops the project plan for implementing the perpetual audit system. The project plan might include

- The time frame of the audit model implementation
- The scope and extent of the three self-audit

- The sequence for performing the self-audits
- The methods and criteria for the self-audits
- The record and reporting mechanism

One of the obstacles in this phase could be the need to relate the results of the self-audits at different levels. Although various solutions might suggest themselves, the underlying principle is that the lower-level audit should be regarded as the extension of the upper one. For instance, any non-conformance during the observations and follow-up in the milli-audit should be audited further in the micro-audit.

(3) The trial project for each type of self-audit is selected based on the audit expertise of the process owner and the intricacy of his or her processes. Prior to a trial audit, the audit's criteria and methods should be documented in simple and concise form. During the trial audit, the quality manager should work closely with the self-auditors, monitoring the audit progress and providing necessary technical assistance. The pilot self-audit should start with a milli-audit, and then move to a micro-audit and nano-audit because this audit trail follows the business process flow.

(4) By analyzing the results of the pilot audit, the auditor can make any necessary changes to the audit plan. The quality manager assembles the self-auditors to review the audit's approach and results in order to facilitate the future full-fledged self-audits. A kick-off meeting, hosted by the quality manager, is used to stress the importance of self-audits and explain the basic audit procedures. The self-auditors involved in the trial project are sent out to

observe the implementation progress and provide technical assistance.

(5) The self-audit reports are summarized and handed out to relevant managers. Self-audits should be reviewed to see if they have been executed according to the planned arrangement. As a result of the review, the amendments to the original audit plan, audit approach and supportive mechanism are made. During this initial stage of the self-audit, management should encourage the auditor to report any meaningful audit findings and provide training on more refined audit techniques if required. Audit records and checklists are documented in an appropriate form for future use.

(6) Management should encourage self-auditors to propose actions to eliminate the root cause of nonconformance. In sequence, corrective and preventive actions are planned and implemented by the steps defined in prescribed procedures. As well, continuous improvement opportunities are identified by comparing the process performance with the relevant targets. Considering the resource limitations, management should prioritize these actions and assign them to the process owner or operator to perform. By doing so, the self-auditors "will gain experience in identifying potential problems and thus more from correction to prevention" (Karapetrovic & Willborn, 2002).

(7) Upon completion of the audit, any improvement actions are verified for their effectiveness and efficiency, and the first self-audits are terminated. Now the perpetual audit system is ready to run according to the predetermined arrangement. As planned, a system audit is performed by an internal auditor to

identify any systematic failure within the QMS. Moreover, internal auditors need to verify that the self-audits have been implemented properly.

(8) At a prescribed frequency, a regular system-wide audit is conducted after the perpetual audit model has been implemented and maintained. As well as being used to identify and address any systematic quality issues, the system audit at this stage has another main function: to verify from a broad perspective that the ongoing self-audits are being conducted as planned. The following elements might be considered in detail when auditing for the effectiveness and efficiency of the self-audit potion of this model:

- Plan: The suitability of the self-audit plan needs to be examined in order to adapt to the ever-changing customer requirements and the system's maturity. As a result, the various self-audits might have to be re-prioritized to ensure that the limited audit resources are appropriately allocated. For example, less frequent self-audits will be made of the more stable processes while the new or unstable process will receive more attention. Another factor to consider is the current quality policy and objectives. When they are changed, the focus will be shifted to the organization's key processes.
- Do: The self-audit approach will be closely examined at this stage. The purpose is to make sure that the self-audit is being conducted as required. Audit components including timing and sampling sizes are examined by reading audit reports as well as observing the audit practices. The auditor's competency is another issue in terms of

achieving audit goals. When necessary, training is provided to maintain the required audit level. The audit checklist or documentation needs to be evaluated as well to find any opportunity for improvement.

- Check: Audit reporting is some of the core content that is subjected to appraisal. As explained, the major function of self-audit reporting is to identify the locations of the system's weaknesses and the strengths. In this model, reporting follows a funnel-up approach so that upper management relies on the self-audit reports generated at the lower-levels. Afterwards, the planning and relevant arrangements of higher-level audits might be adjusted when change is needed. Therefore, the auditing reporting must be presented in a timely and sensible manner through the proper channels.
- Action: The corrective and preventive actions called for by self-audits are the subject at this stage. Self-auditors, within their mandate, can easily adjust their operations to avoid any discrepancies. In contrast, when the solution to nonconformance demands the cooperative efforts from other departments, they are always the weakest link in the chain. In this case, the nonconformance needs to be brought to the attention of supper management in order to involve other function and departments. During the audit, special attention should be given to inter-function communication to ensure that this type of nonconformity is effectively addressed without any delay.

The complete implementation of the perpetual self-audit model is summarized in Figure 4.3.

4.7 Chapter Summary

In this chapter, a perpetual self-audit model for performing three different self-audits throughout a company on a continuous basis was presented. At the corporate level, a system audit is conducted to assess the system's quality performance as well as the status of the self-audit implementation. Process owners carry out a monthly milli-audit to measure the quality of their processes. The unit leaders take the responsibility of evaluating the performance of their sub-processes by implementing a weekly micro-audit. Every day, via a nano-audit, the operator uses a checklist to ensure that his/her operational activities are conforming to the prescribed standard or procedure. By performing these audits, the process owners are empowered to take the initiative to monitoring their own processes, sub-processes or activities.

The following chapter presents a case study in which the two models described in the previous chapters were applied to help a company successfully transform its quality system from ISO 9001:1994 to ISO 9001:2000. This case study serves as strong evidence that these models can feasibly be implemented for ISO 9001:2000 auditing and transition purposes.

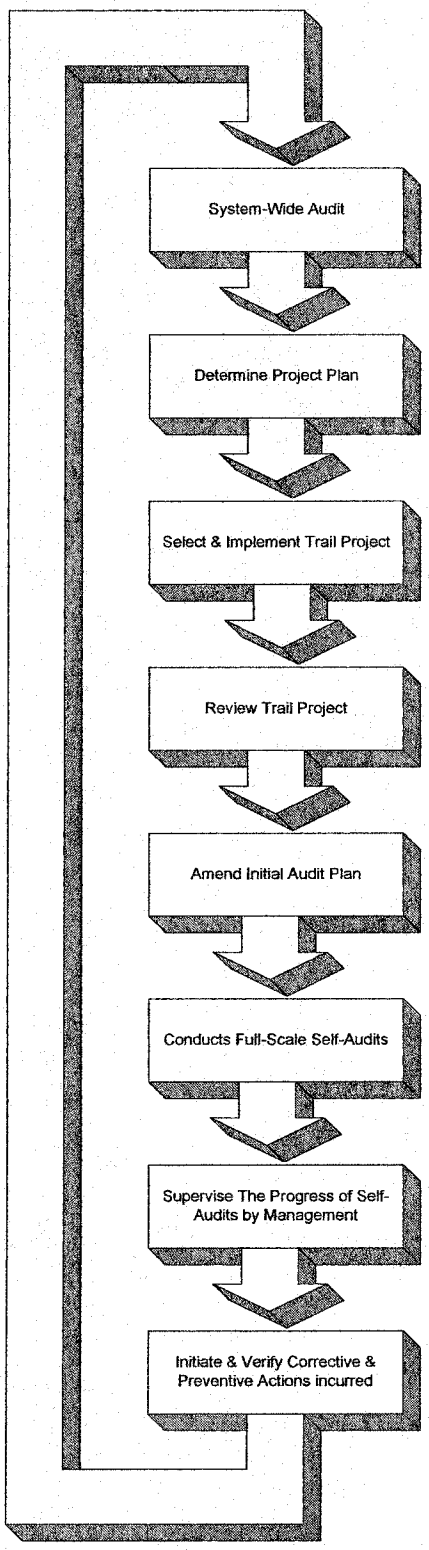

Figure 4.3 Implementation of Perpetual Audit Model

5.0 Audit in upgrading to ISO 9001:2000 QMS: A Case Study

5.1 Introduction

This chapter presents a case in which the audit models defined in the previous two chapters were used to help one company successfully upgrade its Quality Management System from ISO 9001:1994 to ISO 9001:2000. This project serves as a convincing examination of the feasibility of the audit models.

5.1.1 Case Study Company

The company in the case study is an independent design firm for circuit technology used in virtually all mainstream DRAM (dynamic random access memory) products—most commonly used for data storage in personal computers. This company operates in two divisions:

- Division A - Develops networking chips for the communications market
- Division B - Provides engineering memory tests and analysis systems to memory manufacturers.

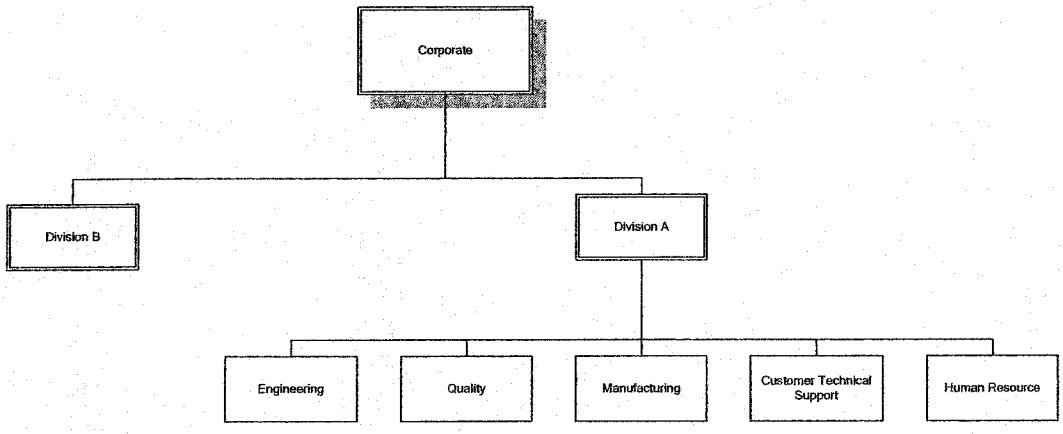

Figure 5.1 Organization Structure

Established and certified in 1994, this company's quality management system includes semiconductor and systems divisions with about 200 employees. This company's Division A has all the quality elements from design to customer service, while only design element is applicable to Division B (Figure 5.1). The design and manufacturing process starts with engineering developing the hardware and software design based on the market forecast generated by manufacturing. With a developed product and engineering specifications, engineers from manufacturing produce the circuit-testing equipment, which is the sole product in the Division A. Materials are purchased through the engineering department. During and after the production, product and quality engineers conduct in-process inspections and final tests prior to the shipments to the customers. The customer technical support group is responsible for training, on-site installation, and servicing for customers. As usual, Human Resources is accountable for recruiting and training new employees. In the Division B, customers assign design tasks to the unit, with certain product and time restraints. The person in charge of the quality management system is the management representative who is also the quality manager in the company. Twice a year, he directs several internal auditors to perform a system audit to review the system's status prior to the arrival of external auditors. In general, this company had a very typical quality system run on the ISO 9001:1994 quality standard.

Given that this was a mature quality system, the company did not need to start a large-scale system revision. As well, at that time, the company was under tight financial and manpower constraints for this project. The most important

thing was that the project was expected to be finished within six months – from June to December, when the external ISO 9001:2000 certification audit took place. All these constraints demanded a quick transition approach with minimal interference to the company's daily operations. If the company had taken a conventional approach, a QMS would have been set up, and then an internal audit would have assessed the system's readiness for an external audit. In this case, obviously, the conventional approach was not a suitable option. First, it usually takes six to twelve months to finish a project like this, which was unacceptable. The most serious downside was that, since the audit was scheduled for the last stage of the project, the company might have realized too late that something was wrong with the system. Therefore, a new transition methodology was deemed urgent.

The main reason for applying the two models illustrated in Chapters 3 and 4 of this thesis is that instead of treating the audit as the last measure, the audit was used to guide the whole transition project. By using the perpetual self-audit model, the quality performance is constantly measured against the desired targets and goals. Accordingly, any discrepancy will be identified and corrected in a timely manner. Therefore, by using this kind of real-time "self-diagnosis" and "self-adjustment", the company could ensure that the system would always run on the right track. As well, since most of the audit task was accomplished by the process owners, who would have been the auditee in a traditional audit, the use of this model did not require the company to hire "extra hands" either internally or externally to be full-time auditors or consultants. Because process owners, who

had the best understanding of the process, were the auditors, they did not have to spend time familiarizing themselves with the system. As well, they ensured that company's improvement strategy would have been the utmost support for its implementation. After the transition was implemented, the process-based ISO 9001:2000 audit model was utilized to assess if the system conformed to the ISO 9001:2000 standard prior to the certification audit. In the following sections, a detailed description of the whole project is provided.

5.1.2 Project

The purpose of this project was:

- To provide a theoretical model for a successful transition from the ISO 9001: 1994 to the ISO 9001: 2000 Quality Management System (QMS) by means of auditing.
- To assist the company in the case study in the transition to ISO 9001: 2000 and to lay the foundation for an effective and efficient quality management system based on internal and self-auditing.
- To promote and facilitate further research into the effectiveness of quality auditing.

The project's scope covers the following activities:

- Design and development of a model for the transition of the company's QMS from compliance with ISO 9001: 1994 to compliance with ISO 9001: 2000.

- Development of a framework for the internal auditing program, including the use of the self-audit concept and process-based audit to facilitate the future ISO 9001:2000 audit.
- Conducting the necessary gap analyses, evaluations and audits of the QMS's compliance with the ISO 9001: 2000 requirements and of the system's effectiveness in achieving the stated quality policy and objectives.

5.2 Transition Project

In this section, the following will be presented

- Project Initiation
- Project Implementation
- Project Review

5.2.1 Project Initiation

After initial contact, a project plan was proposed and approved by the company (Table 5.1).

By applying the models proposed by Ni and Karapetrovic (2003), the whole project was comprised of three stages (Figure 5.2):

Project Initiation – Preliminary data gathering and analysis were the main objectives at this stage. A document review was conducted to review the status of the company's documentation system. Amendments to the documents were suggested to the quality department to in order to facilitate forthcoming transition work. Subsequently, an on-site initial system audit was performed. Because no transition effort had been made yet, the ISO 9001:1994 standard was used as audit criteria. The checklist combined the ISO 9001:1994 internal audit checklist

developed by the company and the follow-up items from the document review. During this stage, the noticeable gaps against ISO 9001:2000 standard were noted in order to calculate the transition workload as well to present the project's prognosis to the management.

TIME	ACTIVITY
May 2002 (one week)	▪ Conduct an on-site gap analysis against the ISO 9001: 2000 requirements. ▪ Propose recommendations for closing the gaps, particularly related to the restructuring of the existing system and adding of new elements.
June – August 2002 (three months)	▪ Develop the framework for ISO 9001: 2000 compliance and transition from the current ISO 9001: 1994-based QMS ▪ Facilitate the changes in the QMS necessary to close the gaps identified in the initial gap analysis and subsequent QMS evaluations, internal and self-audits. ▪ Develop, prepare and facilitate the implementation of an internal audit framework and the required materials, including training programs and audit documentation. ▪ Assist in the implementation and assessment efforts.
October or November 2002 (one week)	▪ Conduct an audit against the requirements of ISO 9001: 2000.

Table 5.1 Project Plan

Project Implementation – The transition work started with the documentation system, which the whole quality system was built upon. Using the output from the previous document review, documentation architecture was developed and used to identify the documents that needed to be compiled and/or amended within a certain amount of time in every department. Afterwards, a number of consecutive.

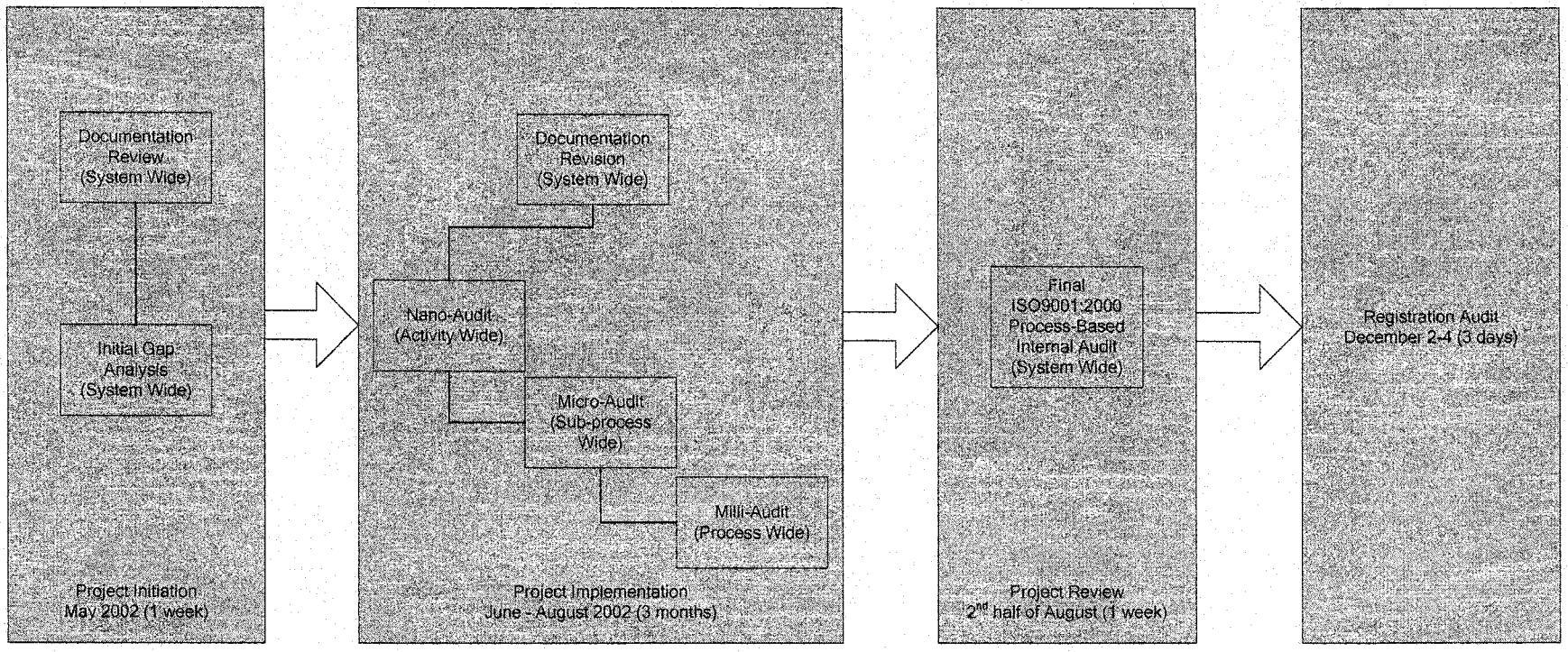

Figure 5.2 Transition Project Overview

milli, miro and nano audits were conducted throughout the company to provide feedback in terms of complying with the ISO 9001:2000 standard. The audit checklists were then condensed from relevant procedures and process maps. As a result, relevant improvement actions were carried out to minimize the variance

Project Review – After several department audits had been conducted, and the improvement actions had been completed, the full-scale ISO 9001:2000 internal audit started to review the system's readiness for the approaching external audit. Process-based audit methodologies were applied as required by the revised standard's requirement. The checklist presented in Table 3.3 was used to guide the whole audit process. The final improvement action plan was established and closely monitored for its progress.

The stages of this plan do not differ from those of any other ISO 9001 implementation project. The core difference between this project and others was the two types of audit approaches that were used.

The document review was conducted based on the quality manual, procedures, and several work instructions provided by the company (Table 5.2). Thanks to their previous efforts put into the ISO 9001:1994 system, this company had a very extensive documentation system. After consulting with the management representative, the company decided to keep the overall documentation structure, modified with necessary amendments, because the company's employees appreciated the value of the existing documents and relied heavily on them in the company's daily operations. Any major omission of documents, which is allowed under new standard, might have resulted in a

malfunction of the associated departments. In terms of documentation compliance per se, no major discrepancy was found at this stage, except that the revised standard elements, i.e. the quality policy, quality objectives and management communications, etc., need to be addressed. Another contribution from this review was that a checklist, as shown in the last column of Table 5.2, for the initial on-site system was developed. Part of the checklist deals with the implementation assessment of the existing documents. As a company grows, many of its documents might become obsolete and hence need to be updated. Another function of this checklist was to identify the current approaches used by the company to deal with the non-descriptive elements, for instance, Section 5.1, Management Commitment, or how the senior management communicates its commitment to satisfying customers and pursuing continuous improvement. As observed during the later part of this project, many non-descriptive elements were applied throughout the company. The unfinished job was to identify them and put the necessary controls in place.

An on-site system audit based on the ISO 9001:1994 standard was performed after the document review. The project facilitator, accompanied by one observer from the company, took three days to assess all the departments involved in the quality system. Two major issues were found during these audits. Although the company had a very extensive documentation system, many documents did not reflect the actual operations. This typical "double-life" scenario could be observed in many mature quality systems. The best example was the engineering documents. According to the design procedure, in addition to the design

ELEMENTS		COMMENTS	CHECKLIST
4 Quality Management System	4.1 General Requirements	N/A	■ Process Identification ■ Sequence and interaction of processes ■ Process Measurement ■ Process control methods ■ Process priority ■ Relevant resources and information ■ Monitoring and measurement ■ Improvement
	4.2 Documentation Requirements	■ No detail specifying **Document Code Name** for **Process Documentation** ■ The **Document Creation Process** within **Semiconductor Division** specified by Documents & Data Control Detailed Procedure contradicts the one in Guidelines for Creating Operating Procedures, Detailed Procedures, and Working Instructions ■ No specific content found in Operating Procedure for Document and Data Control relating to **Identification/Verification/Distribution/Protection of customer-supplied hard copy data**. ■ No content addressing **how to identify and control applicable regulatory or statutory document** ■ No disposition method of quality record specified.	■ Controlled Document scope ■ Document Creation/Revision ■ Master Register ■ Distribution list ■ Review & Approval authority ■ Process for Preliminary Documentation ■ Process for Engineering Released Documentation ■ Confidential Document ■ System: Engineering Change Order ■ Semiconductor: Project Change Request/ Approval Sheet/ Contract Approval Form ■ Generation/Change of Source Control Document ■ Customer-supplied data and program ■ List of Quality Records
5 Management Responsibility	5.1 Management Commitment	N/A	■ Communication method of management commitment ■ How to identify the statutory and regulatory requirements
	5.2 Customer Focus	N/A	N/A
	5.3 Quality Policy	N/A	■ Commitment Complying with requirement Continually improvement ■ Framework for quality objectives ■ Communication and understanding throughout the organization ■ Continually reviewed ■ Distribution control of quality policy and objective

Table 5.2 Document Review Report

verification, the company had a clear-cut design-validation stage in which the produced testing equipment was test-run under the simulated usage conditions. However, in an effort to improve efficiency, the verification and validation stage were mingled together to obtain the test results as quickly as possible. This problem resulted mainly because the documentations had not kept up to date with the relevant operational changes. Another noticeable discrepancy was that the process approach supported by new standard was not available. As illustrated in the previous chapters, one of the fundamental changes in the ISO 9001:2000 revision is that the whole system is viewed as the sum of various processes and sub-processes. By strategy deployment, the overriding quality policy and objectives govern the operation of these processes. In the company in the case study, the processes and even the general corporate objectives were not clearly defined. Compared to the first type of nonconformity, this one was more critical because it required an essential change in the company's approach as well as intensive communication to make employees aware of the problem. The audit results were conveyed to the senior management, and its commitment to support the project was secured. Another problem was caused by the inconsistency between the two divisions. When the quality system was initially established, the company intended that both divisions would follow the same procedure in most aspects. However, due to the essential operational variance, in reality, different approaches were being used in these two divisions.

5.2.2 Project Implementation

Based on the findings from the initial audit, it was determined that the transition work would started with an overhaul of the documentation system. With consent from the departments, documentation architecture (Table 5.3) was handed out with clear task descriptions. Half of the amendment task was to update the existing documents, while the other half was to replace the current clumsy documentation with flowcharts. For instance, a training operating flowchart was used to replace the previous outdated training operating document. The decision to use a flowchart depends on the system's maturity. When employees are familiar with the operation, a flowchart is the best option because of its amendment flexibility and easy-to-read feature. Another benefit of using a flowchart is that it is very easy to identify a process with its elements – input, activity and output.

A complete and applicable flowchart should include the following components:

Responsibilities – A flowchart should identify the persons who own the activities involved in the process. When using a self-audit, appointing these process owners is critical because they are accountable for checking the activity performance within their jurisdiction.

Output – At many points, activities generate various outputs to the following process or department in the form of quality records or documents. The process's status is assessed by reviewing these outputs.

ELEMENT	TITLE	DOCUMENTS	RELATED PROCEDURES	STATUS
4.1	General requirements			
4.2	Documentation requirements			
4.2.1	General			
4.2.2	Quality Manual	*Quality Manual*		
4.2.3	Control of Documents	***Document Control Operating Procedure***	**CORPORATE** Creating Operating Procedures, Detailed Procedures and Work Instructions Network Backup Procedure Reliability Quality Procedure **Division A** Creating or Changing a Bill of Material Creating an Item Master Drawing Guidelines Procedure Part Naming Convention Part Numbering Guideline Product Changes Procedure Release, Control & Distribution of Product Documentation SOCD Procedure ECO Checking Checking ECO Incorporation Checking New "MD" Drawings Checking New "UA" Drawings **Division B** Semiconductor Engineering Change Procedure Document & Data Control Procedure Receipt & Processing of Document	
4.2.4	Control of Quality records	***Control of Quality Records Operating Procedure***	**Division A** Control of Quality Records Procedure **Division B** Procedure for Records Management	
5	Management responsibility			

Table 5.3 Documentation Architecture

Activities – These are the main contents in a process flowchart. Defining these activities provides an opportunity for the process owners, based on an activity's contribution to the overall process performance, to add any necessary activity or delete any unwanted one to help the process to function effectively and efficiently. As well, the owners can streamline the sequence of relevant activities in this process.

Reference – This component involves the applicable documentation that directs the operation of individual activities. Usually when amending, it is very easy to change portions of the documents yet neglect to adjust the impacted activity.

Related Processes – These processes are either previous or subsequent processes which the current process inputs from or outputs to. Their identification serves two purposes:

- To ensure all the input or outputs of current process are identified. When any change is made to the current process, they will be amended accordingly
- During the internal audit, to help the auditor to complete the audit trail by following these processes

Process Measures – As required by the standard, the process performance needs to be measured in terms of achieving predetermined quality objectives. This measurement is accomplished by verifying the quality of either the process output or the process efficiency and effectiveness indicators, such as time, quantity or financial constraints set by the process owners.

When the documentation update was finished, the consecutive self-auditing began to help the company close the gap between the standard requirements and the quality system's operation. The origin of the perpetual self-audit model proposed in this thesis is very interesting. At first, a conventional internal audit was planned to evaluate the implementation status of each department. Every week, one department was selected to be assessed for its project status, and any necessary recommendations for further improvement would be provided. However, during the course of conducting the initial audit of the manufacturing department, we were frequently interrupted. Either the auditee was abruptly called to attend to a situation in the production line, or the audit had to be rearranged because of a conflict with the auditee's schedule. It was realized the since the auditees were so busy, they did have enough time to be interviewed or observed. Therefore, we had to use a different self-audit approach for, otherwise, the routine manufacturing operation would surely have been interrupted. Therefore, a new self-audit model was proposed, as described in Chapter 4. Instead of having just a few internal auditors go around the company to conduct the internal audit, process owners took the initiative to audit their own processes. The whole time-consuming audit program was replaced by a "daily check", which took only 10 minutes at most.

Because of its operational maturity and management proficiency in quality audits, the manufacturing department was picked as the subject of the pilot project using the new self-audit model. A kick-off meeting participated in by the quality representative, internal auditors and manufacturing staff was held. It laid out the

self-audit program, with a sufficient technical explanation of the newly adopted self-audit approach. The manufacturing department carefully prepared the milli-audit checklist with help from two assistants. Specific items, such as the audit data, audit plan and checklist, were decided upon by both the manufacturing director and quality director. The manufacturing director took two days to perform milli-audits on the relevant processes in his department. The author witnessed the whole audit processes and made some technical suggestions regarding the sampling size and subsequent audit arrangement. A thin line existed between the milli-audit and micro-audit in the sense that, during the milli-audit, the auditors always pursued the in-depth evaluation of individual processes. The auditors needed to be reminded that the priority of a milli-audit should be the activities performed at the department level, for instance, how the departmental quality objectives are deployed as well as their relevance to the corporate objectives. Since no major difference existed between the traditional internal audits and the self-audits at this point, they ran very smoothly overall.

The audit findings were kept and handed out to each process owner. Later on, the process owners were asked to plan the micro-audits and prepare for the needed audit documents. Special attention was given to any follow-up item noted on the milli-audit audit report. The product engineer noticed that one observation was about the lack of control of the testing fixture. Since he was the owner of the monitoring and measuring devices control process, he included this observation in his micro-audit plan. The micro-audits were performed with the monitoring of the manufacturing and quality directors. The product engineer found out that the

control of the testing fixtures used by the manufacturing staff did not follow the steps defined in the monitoring and measuring devices control procedure. As well, when reviewing the non-conformance product report, he learned that several customer complaints had been caused by mal-functioning testing fixtures. He proposed to use the methods defined in the procedure to control the testing fixture. According to the procedure, the quality engineer is supposed to verify its testing functions and register the testing fixture prior to use. The product engineer is responsible for the daily check to prevent damage or deterioration. At prescribed intervals, the quality engineer calibrates the testing fixture against the standard. Consequently, four nano-audit checklists and records were developed for the verification, registering, daily check and calibration of the testing fixture. Each checklist was designed to be finished within ten minutes. In two weeks, all these four nano-audits were completed. Follow-up actions were taken by the manufacturing director and product engineer to ensure the control methods of the testing fixtures had been implemented. Also included in this follow-up was the verification of the micro- and nano-audit. These two self-audit reports were checked for their conformity with the audit plans.

Following the same approach demonstrated above, a full-fledged self-audit was carried out throughout the company. The project team met twice a week to discuss the progress and coordinate the efforts of each department. At the end, the project team followed up on all the improvement actions taken.

5.2.3 Project Review

After the self-audit had been finished and the generated corrective actions had been taken, the final process-based system audit was ready to begin to evaluate the system's readiness for the external certification audit. The audit plan for each department was distributed with a detailed description of the audit task. Since the documentation review was included in the Stage 2 of this project, a review did not need to be performed again. In these quality plans (Table 5.4), within each department, the time was specified differently since it had to accommodate the auditee's schedule. This kind of flexibility can be achieved only during an internal audit. General system elements such as 4.1 and 4.2 were evaluated during each department assessment. The audit was performed by applying the methodology illustrated in Chapter 3.

The audit found several minor nonconformities in each department (See the attached audit report). The audit demonstrated that the new self-audit model had effectively helped the company successfully upgrade to the ISO 9001:2000 quality management system. The rest of the time before the certification audit was used to implement the corrective actions.

As planned, the certification audit was conducted on Dec. 2-4 of 2002. According to the audit report, the registrar gave the quality system high marks by stating, "The management team is fully committed to all aspects of ISO 9001:2000, particularly data analysis and improvement". This comment substantiates that the two models were effective in helping the company transform to the ISO 9001:2000 system. As well, the minor non-conformance, involving the

selection of suppliers, found during the certification audit, had also been found during the final internal audit. Thus, the process-based audit model is capable of effectively identifying the discrepancies in a quality system.

In hindsight, the biggest challenge in this project was that, at the beginning, it was very difficult to convince the personnel involved to accept and start using the self-audit models. The careful planning of the trial project was very important because it had to have exemplary effects to alleviate the staff's doubts. Since using the three types of self-audits was something new to the employees, management support was critical to enforce and follow up implementation. One improvement that could be made in a future similar project would be to shorten the waiting time between the final internal audit and the certification audit because maintaining the momentum over a long period of time is very difficult.

5.3 Chapter Summary

Chapter Five presented a case study in which the two models – the process-based ISO 9001:2000 audit model and the perpetual self-audit model were utilized to help a company successfully transform its quality system from ISO 9001:1994 to ISO 9001:2000. The project consisted of three stages: the project initiation stage included the planning of whole project, followed by a documentation review to provide an initial understanding of the system, as well as by an initial gap-analysis audit to assess the actual workload in the subsequent stages. The project implementation stage started with documentation revision to ensure that ISO 9001:2000 was clearly defined. Another critical task in this stage was to develop the three levels of the perpetual self-audit model. A trial project

served as a test to determine the suitable forms of the self-audits. After the outcome was reviewed, the full-fledged self-audits were implemented throughout the company. During the last stage of this project, which was the project review, a process-based ISO 9001:2000 internal audit was conducted to evaluate the system's readiness for the forthcoming certification audit. The discrepancies found in the audit were corrected with improvement actions.

Internal Audit Plan

AUDIT OBJECTIVE

To review the progress of the quality management system transition and to identify the areas for future improvement

AUDIT SCOPE

Case study company Division A

AUDIT STANDARD

ISO 9001: 2000 Quality Management Systems – Requirements

AUDITOR

System facilitator

SCHEDULE

TIME	FUNCTIONS	RELEVANT ELEMENTS
Aug 12 10:00-11:00 AM Aug 13 9:30-11:00 AM	CTS Administration	7.2 Customer-related process 7.5 Production and service provision
Aug 13 1:30-3:30 PM	DUT Card	7.3 Design and development 7.4 Purchasing 7.5 Production and service provision
Aug 14 1:30-2:30 PM	Training Application	7.5 Production and service provision 8.3 Control of nonconforming product

Please note that the following elements will be audited for each function:

4.1 General Requirements
4.2 Documentation Requirements
5.5 Responsibility, authority and communication
6 Resource management
8.4 Analysis of data
8.5 Improvement

INTERNAL AUDIT REPORT

DEPARTMENTS/FUNCTION	Customer Technical Support (C.T.S.)
AUDITEE	
AUDITOR	System facilitator
AUDIT DATE	Aug 13-14, 2002
AUDIT STANDARD	ISO 9001:2000
PROCESS AUDITEED	7.2 Customer-related Process 7.3 Design and development 7.5 Production and service provision 8.3 Control of nonconforming product
FUNCTION AUDITED	Service (7.2/ 7.5/ 8.3) DUT Card Control (7.3/ 7.5/ 8.3) Application & Training (7.2/ 7.5/ 8.3)
PROCEDURE AUDITED	Customer–related Flowchart Design Control Operating Procedure Control of Nonconforming Product Operating Procedure Control of External Nonconforming Product Procedure

General

This internal audit is intended to assess the implementation status of ISO 9001: 2001 QMS in the company. The audit will be conducted on the functions listed above. Any discrepancy found during the audit will be presented for improvement before the initial certification scheduled on Dec. 2-4, 2002.

Summary

The current processes involved in the service in the C.T.S. are effective and well documented. The relevant information coming from the customers is effectively communicated to other departments and followed up. The customer satisfaction information is being continuously monitored, although a more defined approach is expected in the future.

Service: the requirements on the customers' purchase orders have been effectively reviewed to ensure that the company has the capability to satisfy the customers. A comprehensive record has been used to keep the track of

customer requirements. The problems filed by customers have been recorded and passed on to the relevant application engineers and other functional personnel to handle. The customer properties have been clearly identified and listed to prevent their unsuitable use.

DUT Card Control: The DUT Card design and fabrication process follow the steps specified in the DUT Card Development Process. The criteria and methods for verifying the purchased product – DUT Card drawing and fabrication are recommended to be established by the auditor to ensure the quality of the DUT Card. Also, there is no evidence to show that customer-provided external documents, such as K4D26323RA-GC, are identified and controlled for their distribution.

***Application & Training*:** Hardware and software customer support follow the steps specified in the Control of External Nonconforming Product Procedure. An extensive database has been established to trace and review any problem reported by customers. However, it is recommended that the process involved in the training provision be documented. The training material should be controlled as per Document Control Operating Procedure.

Findings:

Minor Nonconformances;

1. The acceptance criteria and methods for verifying the purchased products – DUT Card and drawings are not available to ensure their quality. (ISO 9001: 2000 7.4.3)
2. There is no evidence to show that customer-provided external documents, such as K4D26323RA-GC, are identified and controlled for their distribution. (ISO 9001:2000 4.2.3)
3. The training material is not controlled against the requirements defined in the document control procedure. (ISO 9001: 2000 4.2.3)
4. There is no evidence to show that the ability of the testing program for inspecting the DUT Card has been confirmed prior to initial use. (ISO 9001:2000 7.6)

6.0 Conclusions

This chapter discusses the main contributions of the work presented in this thesis, followed by recommendations for future research.

6.1 Contributions of the Research

Chapter Three presented a process-based quality audit model. The concepts came from the application of process management principals to the ISO 9001:2000 quality management system. Following the business operational flow, the processes involved in the standard were restructured as six major processes: the strategic deployment process, system planning process, resource provision process, implementation process, monitoring and measurement process and improvement process. Based on these processes, two levels of the audit in the process-based quality audit model were discussed. The top management audit is used to assess how the quality policies and objectives are related to the customer requirements and the company's long-term strategy. The department audit is used to evaluate the performance of individual departments. The focus is on the following process essentials: process boundary, process input, process output, process ownership, sub-processes and their sequences, process control methods, process performance metrics, process performance measurement, and improvement.

The benefits of the model include

- It addresses the question of how to audit according to the ISO 9001:2000 standard by providing a generic framework that can be applied in various business settings.

- It provides a value-added service to the auditee by taking his or her operational characteristics into account. It helps the auditee to establish a quality system that are integrally embedded in the organization's daily operations.
- This model fosters continuous improvement promoted by the 2000 revision of the ISO 9001 standard. Auditors look for evidence of process improvement when evaluating the process performance metrics and measurement.

Subsequently, the possible application of this model was discussed, followed by a checklist that could guide the whole audit process.

Chapter Four dealt with a perpetual auditing model for upgrading a quality management system to ISO 9001:2000. The model is based on the synergy of combining regular system audit and self-audits. Three levels of self-audit - micro-audit, milli-audit and nano-audits - are carried out to evaluate the quality performance of, respectively, process, sub-process and activities. Process owners, instead of the external auditors, take responsibility for self-audits. Therefore, these owners are motivated to closely monitor their own operations and to improve their performance when needed. Since each of these self-audits take only a small amount of time to accomplish, the self-audit model could be implemented on a regular basis, namely, monthly, weekly and daily. It enables a real-time self - diagnosis and subsequent self-adjustment that ensures the quality system is running in the right direction. A company intending to use this model should have major quality system elements and have gained experience with audits. The most

important condition of successful application this model is management commitment. Prior to the implementing of this model, sufficient training is necessary to get process owners well prepared for the forthcoming self-audits. The possible application of this model was detailed in the later part of Chapter Five.

Chapter Five presented a case study in which the two models proposed in the previous chapters were used to assist a company to transfer its quality system to the ISO 9001:2000 quality system. The project started with an initial documentation review and gap analysis to obtain an assessment of the company's current status prior to the transition effort. During the project implementation, based on the findings of the gap analysis, the documentation system was revised to conform to the standard. When the system had been clearly and correctly defined, a full-fledged self-audit took place to monitor whether the required process control was in place by constantly measuring and improving the performance against the predetermined targets and goals. During the last stage, the process-based quality auditing model was applied to assess the readiness of the system for the forthcoming certification audit. The project was successfully finished with only one minor nonconformance found by the external registrar.

6.2 Suggestions for Further Research

The following are recommended issues for further research:

- Although the process-based quality audit model was used in the internal audit, this model has not been used in a third-party certification setting.

The implementation of this model in an external audit is expected and should be the subject of further research.

- The application of perpetual self-audit models should be extended to other quality management initiatives, such as pursing the business excellence model.
- The performance metrics to measure the efficiency of these two models should be established.
- Quality costs need to be integrated into the models
- Software programs to assist the implementation of these models need to be developed.

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APPENDICES

APPENDIX I

Process-Based Quality Audit Checklist

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
4.1	**General requirements**							
	Has the department identified the process needed for QMS? If so, what are those processes?							
	By what kind of methods have those processes been defined?							
	Have the inputs and outputs of the process been determined? What are the inputs and outputs requirements?							
	Are the process sequences correct?							
	Are the interacted processes been determined? If so, Are the deliverables between these processes been defined?							
	What are the control methods to ensure the process operation effective?							
	What process criteria have been determined to ensure the effectiveness of the control methods							
	What kind of resources and information are needed in order to control and monitor these processes? Are current resource and information sufficient?							
	How are the process monitored in terms of its effectiveness? What data have been recorded?							
	How have relevant personnel analyzed the monitoring data? What follow-up actions have been taken?							
	How has department addressed the continuous improvement of these processes?							
4.2.3	**Control of Documents**							
	What procedures are applicable to the department/function audited?							
	Are the latest versions of those documents available on the site? If so, are the revision numbers the same as those in the document master registry?							
	How are the responsibilities for approval, issue, distribution, and administration of these procedures defined in the applicable document control procedure? Please make sure those requirements are followed.							
	Have the amendment contents been recorded in the revision history?							
	Are the documents formats compliant to the relevant requirements specified in the procedures?							
	Is there any obsolete document available on the site? If so, is the document marked "superseded"?							
	What documents from external origins does the department/function have? Are the external documents registered and distributed according to the processes required by the relevant document control procedures?							
	Is there any electronic copy of document or software program used by the department/function? Have these softcopy or program been controlled as per relevant document control procedures							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
4.2.4	**Control of Records**							
	Are the records used by the department/function the same as those in the applicable procedures?							
	What are responsible and authorities for filling out, reviewing and approving of these records prescribed by the quality record procedure? Are those requirement followed in the department/function audited?							
	Where are the records kept and stored? Is it easy to retrieve record by using current keeping and storing methods?							
	How long the quality record should been retained?							
	What are the disposal methods for records beyond the specified retention period?							
	What kinds of electronic record are used by the department/function? Is there any requirement specified in the record control procedure about the identification, storage, protection, retrieval, retention time and disposition of these records? If so, are those rules followed?							
	What are the disposal methods for records beyond the specified retention period?							
8.2.3	**Monitoring and measuring of processes**							
	If applicable, what are the process performance measures for the department /function?							
	What are target values for those process performance measures?							
	What are the monitoring and measurements methods employed to obtain the data for the prescribed process performance measures?							
8.4	**Analysis of data**							
	What kind of methods are used by the department /function to analyze the data collected relevant to: 1) Customer satisfaction 2) Product performance 3) Process performance Supplier performance							
	Who are responsible for analyzing these data? When the data are found not conforming to the relevant requirement or not achieving target value, what action has been taken?							
	If corrective and/or preventive action has been used, have those actions followed the steps defined in the corrective and preventive action procedures?							
8.3	**Control of nonconforming product**							
	What kinds of nonconforming product applicable to the department/function audited?							
	What are the disposal methods for these nonconforming products?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
8.3	**Control of nonconforming product**							
	Which departments and who are involved in the disposition of these nonconforming products? Does it comply with the responsibilities and authorities specified in the nonconforming product procedure?							
	If customer is affected by the disposition, has customer been notified? When appropriate, has the customer approval been gained for the disposition arrangement?							
	What is the identification used for the nonconforming product to prevent its unintended use or delivery/ Have records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, been taken?							
	Is there any evidence to show that the nonconforming product has been reinspected or reverified after rework, reprocess or repair? For nonconforming product found in the customer site,							
	what action should be taken to correct the nonconformity?							
8.5.2	**Corrective action**							
	According to corrective action procedure, what corrective actions are applicable to the department/function audited?							
	What authorities and responsibilities are specified to handle corrective action in the procedure?							
	Have all the corrective actions been closed or followed?							
	Has any applicable information pertaining to the corrective action recorded?							
	Have the cause of nonconformities been correctly detected in a timely manner?							
	Have the remedial actions been decided and taken to minimize the impact of nonconformities?							
	Have the corrective actions been determined, evaluated and implemented to prevent the reoccurrence of nonconformities?							
	Have the corrective action taken been reviewed by appropriate authorities?							
	Are the above requirements prescribed in corrective action procedure or any other applicable procedure?							
8.5.3	**Preventive action**							
	What methods have been used by the department/function to identify potential nonconformities?							
	What methods have been used to analyze the cause of the potential nonconformities?							
	How has the department/function evaluated the need for action to prevent nonconformities from occurring?							
	When deemed necessary, how the preventive action has been determined and implemented?							
	Have the preventive action been reviewed by appropriate authorities?							
	Has the information regarding the results of action taken recorded?							
	Are the above requirements prescribed in preventive action procedure or any other applicable procedure?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.1	**Planning of production realization**							
	What information is needed for planning or scheduling production? Has the communicative channel been established to facilitate to input these information into the production scheduling?							
	Which departments are involved in product scheduling? Could current approach of production scheduling ensure the requirements of customer order?							
	When production plan is made, how could the plan be informed to relevant departments and personnel?							
	Has the quality objectives and requirements for the product been defined during production planning stage?							
	How necessary processes, documents and resources are arranged and provided in order to achieve the production plan?							
	How could production plan be transferred in specific working order, material arrangement?							
	What testing or inspection activities are needed for the determined production plan? How these testing and inspection activities are arranged to be compatible with production plan?							
	Which mechanism is used to record the status of production plan?							
	How the production schedule is reviewed for its fulfillment?							
	When production plan is not achieved, what further action has been taken?							
	How the change to production plan has been changed, when applicable? How the changed production plan has been informed to the affected department or stuff?							
7.2	**Customer-related process**							
	Which department is responsible for obtaining customer enquiry and/or order? By which media these enquiries and/or order have been recorded and communicated to relevant departments/ functions?							
	When necessary, how could the undefined customer requirement be determined by the relevant departments? Which departments are involved in reviewing the customer order?							
	Which items in the customer orders each department should review? Have responsibilities and authorities been clearly defined by the company?							
	Which department is responsible for tracking the statutory and regulatory requirements, such as standards applicable to the product specification? Which methods have been used to obtain the latest information about these requirements?							
	What necessary information are needed in order to make sure that the company has the ability to meet the defined requirements?							
	When there is discrepancy between customer requirements and company's capabilities, how could this discrepancy be resolved?							
	Who has the authority to conform the customer order?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.2	**Customer-related process**							
	When customer orders are changed, how could the changed information be communicated to relevant departments and correspondent adjustments be made?							
	After the review, when it is found that the customer order can't be satisfied, has the customer been notified? Has any change to the order been approved by the customer?							
	What kind of mechanism the company is taking for customer communication?							
7.4.1	**Purchasing process**							
	How many types of supplier form which company has purchased product or service?							
	Is an approved supplier list kept updated? If there any classification of these suppliers based on the effect of the purchase product or service, or on their abilities to meet the company's requirements? If so, what classification methods are used? Have all the relevant departments been notified of the classification information of their suppliers?							
	What criteria for selection, evaluation and re-evaluation have been established for suppliers?							
	Have the records of the evaluation results, disposition and necessary action been maintained?							
	If there is any change to the status of suppliers, could involved departments/function be informed in a timely manner?							
7.4.2	**Purchasing information**							
	How the purchasing request and purchasing order are processed by relevant departments?							
	Are the adequate information contained on the purchasing order including where appropriate a) Requirements for approval of product, procedures, processes and equipment b) Requirements for qualification of personnel, and c) Quality management system requirements							
	Has the purchasing order been approved by appropriate authorities before they are sent to suppliers?							
	Which steps should be followed when the purchasing order has to be changed?							
7.5.1	**Control of production and service provision**							
	Are the information pertaining to the product characteristic, such as product specification, drawing and Bill Of Material, available on the manufacturing site? Are the working instructions available on the manufacturing site, as necessary?							
	Have all the above documents been controlled? (Refer to General Elements 4.2.3 Control of documents)							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.5.1	**Control of production and service provision**							
	Have the materials been delivered to the manufacturing staff timely, correctly and sufficiently? If there is some material deficiency, what steps should be followed to supplement them?							
	Are the suitable production equipments determined and provided in order to achieve the production plan and customer order?							
	Are the suitable testing and inspection equipments determined and provided in order to achieve the production plan and customer order?							
	Has the working environment, including temperature and ESD, been maintained as per relevant documents?							
	Have the manufacturing staffs been adequately trained? What are their qualification criteria?							
	When necessary, have the in-process testing and inspection been performed to measure the product characteristics? Are relevant in-process testing and inspection criteria available? Have the results of such testing and inspection been recorded?							
	What are the requirements for releasing products? Have those requirements been fulfilled?							
7.5.2	**Validation of process for production and service provision**							
	Is there any process for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement? If so, does the department/ function validate these processes?							
	Is there any process for production and service provision where deficiencies become apparent only after the product is in use or service has been delivered? If so, does the department/ function validate these processes?							
	What process parameters and applicable criteria have been defined in order to monitor the process for production and service provision?							
	When appropriate, has the equipment used for production and service provision been approved? When appropriate, has relevant personnel been qualified? If so, has the qualification requirement been defined?							
	What specific methods and procedures have been used for these processe4s?							
	Have relevant records been established in order to continuously monitor the process performance?							
	How the processes are revalidated when necessary?							
7.5.3	**Identification and tracebility**							
	What identification methods are used by the manufacturing staffs? Could current identification prevent nonconforming material or product from unintended use?							
	Where are the identification records kept?							
	Who are responsible for issuing and making the product identification throughout the production and service provision process?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.5.3	**Identification and tracebility**							
	What traceability methods are used by the manufacturing stuff?							
	Where are the traceability records kept?							
7.5.4	**Customer Property**							
	What customer properties, such as customer-provided documents, drawings, testing program, fixture, samples, are available in manufacturing department/function?							
	How these customer properties identified?							
	Have these customer properties been verified when they are received by the company?							
	What protection methods have been taken for these customer properties/							
	Has the situation been recorded and reported to customer when customer properties are found lost, damage or otherwise unsuitable?							
7.5.5	**Preservation of product**							
	How the material and products are handled during the production and delivery? Are the handling requirements documented when necessary?							
	What are the packaging methods for product? Have these packaging methods been validated?							
	Could the current packaging methods meet the requirements when the packaging is part of customer order?							
	Where the products and materials are stored? Are the current storage methods and environment be able to prevent the deterioration of products and materials?							
	Has the environment element, such as temperature or humidity, been checked and recorded when there are relevant requirements?							
	Is there any expired material being used? What relevant staff should do when any expired material is found? What protection measures have been taken for product and material?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.3.1	**Design and development planning**							
	During the design and development planning, has the department/function determine the design and development stages?							
	Has the design review, design verification and design validation been determined during design planning?							
	Have the responsibilities and authorities relevant to the design and development project been clearly defined?							
	Have the interfaces between different functional groups involved in design and development been clearly defined?							
	How are the authorities and authorities defined regarding determining, reviewing and approving design plan? Are these requirements followed?							
	Has the design planning documentation been established, communicated, reviewed and updated by relevant functional groups?							
7.3.2	**Design and development inputs**							
	What are defined in relevant procedures as design inputs? Have these inputs been recorded?							
	Have functional and performance requirements been included in design inputs?							
	How the applicable statutory and regulatory requirements been identified, determined, obtained? If there are external documents available, please refer to General Elements 4.2.3 Control of Documents for auditing.							
	Where applicable, has information derived from previous similar designs been included in design and development inputs?							
	What are other requirements deemed by engineering department/function as essential for design and development activities?							
	Which functional groups are involved in reviewing design and development inputs for its adequacy, completeness and clarity? Please ensure relevant responsibilities and authorities requirements are followed?							
7.3.3	**Design and development outputs**							
	Are the outputs of design and development provided in a form that enables verification against the design and development input?							
	Are the outputs of design and development approved prior to release?							
	Do the design and development outputs meet the input requirements for design and development?							
	Do the design and development outputs provide appropriate information for purchasing, production and for service provision?							
	Do the design and development outputs contain or reference product acceptance criteria?							
	Do the design and development outputs specify the characteristics of the product that are essential for its safe and proper use?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO	QUESTIONS	CP	IP	MI	MA	NA		
7.3.4	**Design and development review**							
	Have systematic reviews of design and development been conducted at suitable stages?							
	Do these reviews a) evaluate the ability of the results of design and development to fulfill requirements b) Identify any problems and propose necessary actions?							
	Do the participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed?							
	Are records of the results of the reviews and any necessary actions maintained?							
7.3.5	**Design and development verification**							
	What design activities are defined as design verification by the design function?							
	Has verification been performed to ensure that the design and development outputs have net the design and development input requirements?							
	Have records of the results of the verification and any necessary actions been maintained?							
7.3.6	**Design and development verification**							
	What design activities are defined as design verification by the design function?							
	Has design and development validation been performed in accordance with planned arrangements (refer clause 7.3.1)?							
	Does the validation ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application?							
	Where practical, has the validation been completed prior to the delivery or implementation of the product?							
	Have records of the results of validation and any necessary actions been maintained?							
7.3.7	**Design and development changes**							
	Have design and development changes been identified and records maintained?							
	Have the changes been reviewed, verified, and validated as appropriate, and approved before implementation?							
	Does the review of design and development changes include evaluation of the effect of the change on materials and already delivered product?							
	Have records of the results of the review of changes and any necessary actions been maintained?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.4.1	**Purchasing process**							
	What kinds of supplier are used by the engineering group?							
	Are these suppliers listed on the Approved Vendor List with their current status?							
	Has the purchasing followed the steps specified in purchasing procedure?							
	What criteria for selection, evaluation and re-evaluation have been established for suppliers?							
	Have the records of the evaluation results, disposition and necessary action been maintained?							
7.4.2	**Purchasing information**							
	How the purchasing request and purchasing order are processed by engineering group?							
	Are the adequate information contained on the purchasing order including where appropriateRequirements for approval of product, procedures, processes and equipmentRequirements for qualification of personnel, and Quality management system requirements							
	Has the purchasing order been approved by appropriate authorities before they are sent to suppliers?							
	Which steps should be followed when the purchasing order has to be changed?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO	QUESTIONS	CP	IP	MI	MA	NA		
7.2	**Customer-related process**							
	Who is responsible for obtaining customer enquiry and/or order? By which media these enquiries and/or order have been recorded and communicated to relevant departments/ functions?							
	When necessary, how could the undefined customer requirement be determined by the relevant responsibility? Which other departments are involved in reviewing the customer order?							
	Which items in the customer orders each involved personnel and department should review? Have responsibilities and authorities been clearly defined by the company?							
	Who is responsible for tracking the statutory and regulatory requirements, such as standards applicable to the product specification? Which methods have been used to obtain the latest information about these requirements?							
	What necessary information are needed in order to make sure that the company has the ability to meet the defined requirements?							
	When there is discrepancy between customer requirements and company's capabilities, how could this discrepancy be resolved?							
	When customer orders are changed, how could the changed information be communicated to relevant departments and correspondent adjustments be made?							
	After the review, when it is found that the customer order can't be satisfied, has the customer been notified? Has any change to the order been approved by the customer?							
	What kind of mechanism the company is taking for customer communication?							
7.5.1	**Control of production and service provision**							
	Are the information pertaining to the product or service characteristic, such as product specification, drawing and Bill Of Material, available on the C.T.S.? Are the working instructions available for the relevant engineers, as necessary?							
	Have all the above documents been controlled? (Refer to General Elements 4.2.3 Control of documents)							
	Have the products, parts or service been delivered to the manufacturing staff timely, correctly and sufficiently? If there is some material deficiency, what steps should be followed to supplement them?							
	Are the suitable service provision facilities determined and provided in order to satisfy the customer orders?							
	Are the suitable testing and inspection equipments determined and provided in order to satisfy the customer orders?							
	Has the working environment, including temperature and ESD, been maintained as per relevant documents?							
	Have relevant engineers been adequately trained? What are their qualification criteria?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.5.1	**Control of production and service provision**							
	When necessary, have the in-process testing and inspection been performed to measure the product and service characteristics? Are relevant in-process testing and inspection criteria available? Have the results of such testing and inspection been recorded?							
	What are the requirements for releasing products or service? Have those requirements been fulfilled?							
7.5.2	**Validation of process for production and service provision**							
	Is there any process for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement? If so, does the department/ function validate these processes?							
	Is there any process for production and service provision where deficiencies become apparent only after the product is in use or service has been delivered? If so, does the department/ function validate these processes?							
	What process parameters and applicable criteria have been defined in order to monitor the process for production and service provision?							
	When appropriate, has the equipment used for production and service provision been approved? When appropriate, has relevant personnel been qualified? If so, has the qualification requirement been defined?							
	What specific methods and procedures have been used for these processe4s?							
	Have relevant records been established in order to continuously monitor the process performance?							
	How the processes are revalidated when necessary?							
7.4.1	**Purchasing process**							
	What kinds of supplier are used by the C.T.S.?							
	Are these suppliers listed on the Approved Vendor List with their current status?							
	Has the purchasing followed the steps specified in purchasing procedure?							
	What criteria for selection, evaluation and re-evaluation have been established for suppliers?							
	Have the records of the evaluation results, disposition and necessary action been maintained?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO	QUESTIONS	OP	IP	MI	MA	NA		
7.4.2	**Purchasing information**							
	How the purchasing request and purchasing order are processed by C.T.S.?							
	Are the adequate information contained on the purchasing order including where appropriateRequirements for approval of product, procedures, processes and equipmentRequirements for qualification of personnel, and Quality management system requirements							
	Has the purchasing order been approved by appropriate authorities before they are sent to suppliers?							
	Which steps should be followed when the purchasing order has to be changed?							
7.5.4	**Customer Property**							
	What customer properties, such as customer-provided documents, drawings, testing program, fixture, samples, are available in C.T.S.?							
	How these customer properties identified?							
	Have these customer properties been verified when they are received by the company?							
	What protection methods have been taken for these customer properties/							
	Has the situation been recorded and reported to customer when customer properties are found lost, damage or otherwise unsuitable?							
8.2.1	**Customer satisfaction**							
	What methods have been used by C.T.S. to obtain the information of customer satisfaction?							
	Which characteristics/parameters related to product or service have been used to monitor the customer satisfaction? Is there any target value that have been set up by the company to evaluate current status of customer satisfaction?							
	How will information of customer satisfaction has been analyzed? Please refer to General Element 8.4 Analysis of data.							
	Has any further action been taken when customer satisfaction doesn't meet the target value?							
	Has the information of customer satisfaction been effectively communicated to relevant departments and managements?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO	QUESTIONS	CP	IP	MI	MA	NA		
7.4.3	**Verification of purchased product**							
	Have incoming inspection been performed?							
	What incoming inspection criteria have been used? Have these criteria been effectively approved for its accuracy and adequacy? Have the incoming inspection been conducted as per these criteria?							
	What sampling plan has been used?							
	Have the incoming inspection results been recorded and approved by relevant responsibilities and authorities?							
	Have the inspector been properly trained and qualified?							
	Have the testing equipments for incoming inspection been calibrated or verified?							
	Which steps should be followed when the incoming material is found out of specification?							
	Where the organization or its customer intends to perform verification at the supplier's premises, has the organization stated the intended verification arrangements and method of release in the purchasing information?							
8.2.4	**Monitoring and measurement of product**							
	What characteristics of the product have been monitored and measured to verify that product requirements are fulfilled?							
	According to test plan, when the monitoring and measurement activities take place?							
	What monitoring and measurement criteria have been used? Have these criteria been effectively approved for its accuracy and adequacy? Have monitoring and measurement been conducted as per these criteria?							
	What sampling plan has been used?							
	Have monitoring and measurement results been recorded and approved by relevant responsibilities and authorities?							
	Have the inspector been properly trained and qualified?							
	Have the testing equipments for monitoring and measurement been calibrated or verified?							
	Which steps should be followed when the product is found out of specification?							
	Is it ensured that product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer?							

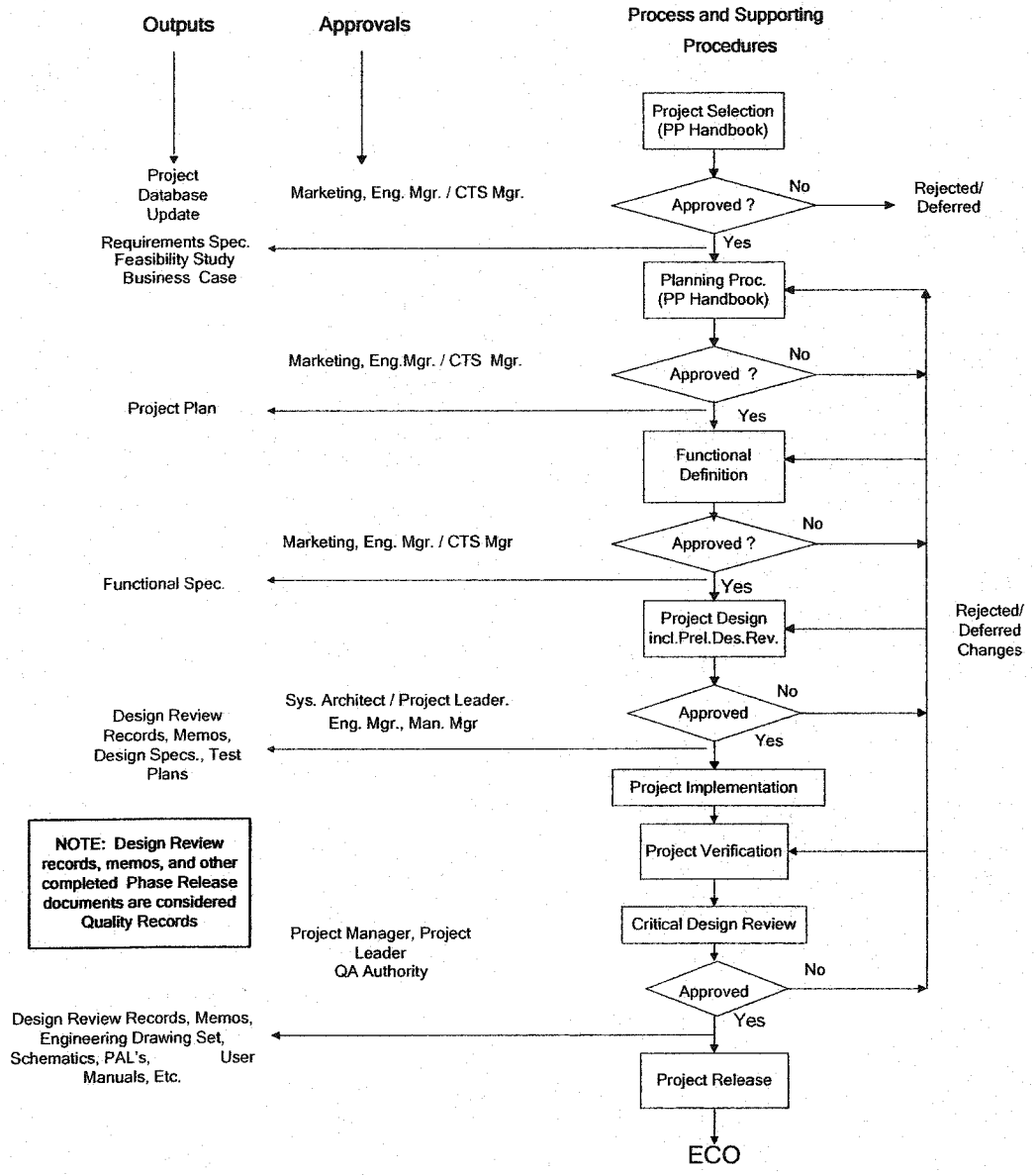
AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
7.6	**Control of Monitoring and measurement devices**							
	How many types of monitoring and measurement devices, including testing fixture and testing software, have been used by the company?							
	What king of methods have been used to control these monitoring and measurement devices?							
	Could these methods ensure the monitoring and measurement requirements can be satisfied?							
	Where necessary to ensure valid results, is the measuring equipment: Calibrated or verified at specified intervals, or prior to use (for testing software used) ?							
	Has the calibration been done against measurement standards traceable to international or national measurement standards? If so, how the international or national are retrieved?							
	Where no such standards exist, has the relevant calibration and verification criteria and procedure been established?							
	Where necessary to ensure valid results, is the measuring equipment adjusted or re-adjusted as necessary?							
	Has the calibration status been identified?							
	Has the monitoring and measuring devices been safeguarded from adjustments that would invalidate the measurement result?							
	Has the monitoring and measuring devices been protected from damage and deterioration during handling, maintenance and storage?							
	Are records of the results of calibration and verification maintained?							
	Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements? Does the organization take appropriate action on the equipment and any product affected?							
	Has company confirmed the ability of testing program prior to initial use and reconfirmed as necessary?							
4.2.1	**General**							
	Has the quality management documentation system included Documented statements of a quality policy and quality objectives? A quality manual?							
	Documented procedures required by this standard (six mandatory procedures, as follow)? 4.2.3 Control of documents 4.2.4 Control of quality records 8.2.2 Internal audits 8.3 Control of nonconformity 8.5.2 Corrective action 8.5.3 Preventive action							
	Other documents needed by the organization to ensure the effective planning, operation and control of its processes?							
	Records required by this standard?							

AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
4.2.2	**Quality Manual**							
	Has the organization established and maintained a quality manual that includes: a) The scope of the QMS, including details of and justification for any exclusions?							
	b) The documented procedures established for the QMS, or reference to them?							
	c) A description of the interaction between the various processes of the QMS?							
5.1	**Management Commitment**							
	Has the organization's top management provided evidence of its commitment to the development and implementation of the QMS, and of continually improving its effectiveness by: Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements?							
	Establishing the quality policy?							
	Ensuring that quality objectives are established?							
	Conducting management reviews?							
	Ensuring the availability of resources?							
5.2	**Customer Focus**							
	Has top management ensured that customer requirements are determined and are fulfilled with the aim of enhancing customer satisfaction?							
5.3	**Quality Policy**							
	Has top management ensured that the quality policy is appropriate to the purpose of the organization, for example, the Business Plan?							
	Has top management ensured that the quality policy includes a commitment to comply with requirements, and a commitment to continually improve the effectiveness of the QMS? Who has the responsibility and authority to establish, review approve and revise the quality policy?							
	Has top management ensured that the quality policy provides a framework for establishing and reviewing quality objectives?							
	Has top management ensured that the quality policy is communicated and understood within the organization? If so, please specify the method of communication							
	Has top management ensured that the quality policy is reviewed for continuing suitability? And how? When the quality policy is found unsuitable, how should the quality policy be revised?							

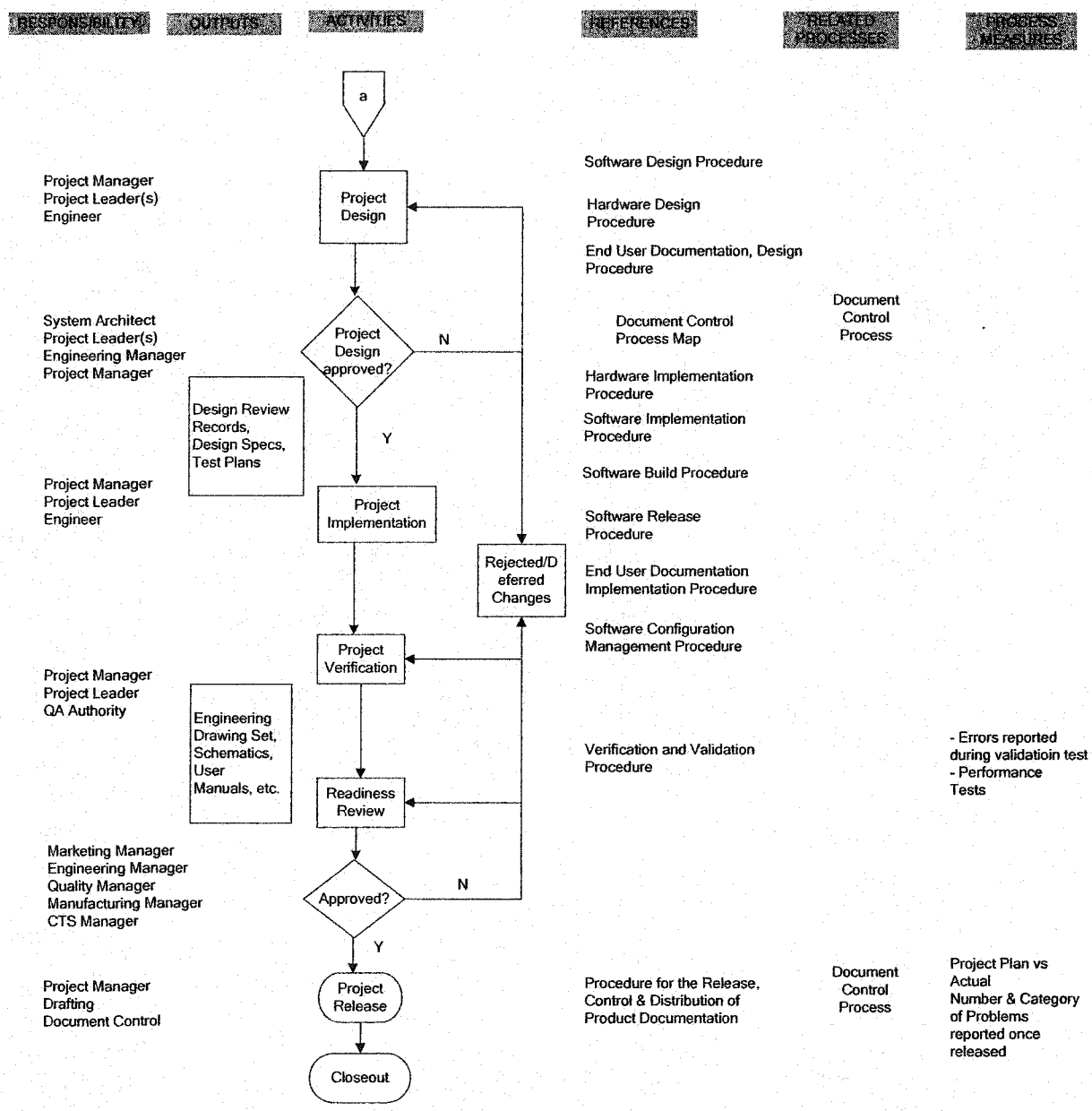
AUDIT CONTENTS		AUDIT STATUS					AUDIT FINDINGS	DOCUMENTS & RECORDS
REF NO.	QUESTIONS	CP	IP	MI	MA	NA		
5.5.2	**Management representative**							
	Who is appointed as management representative? Does his or her responsibility and authority include Ensuring that processes needed for the QMS are established implemented and maintained? Reporting to top management on the performance of the QMS and any need for improvement? Reporting to top management on the performance of the QMS and any need for improvement?							
5.6	**Management review**							
	Has management review conducted by top management to review the continuing suitability, adequacy and effectiveness of quality management system? How frequent management review will be conducted? Who are involved in management review? Does management review include the information of ▪ Quality policy and quality objectives ▪ Results of external and internal audits ▪ Customer feedback ▪ Process Performance and product conformity ▪ Status of preventive and corrective actions ▪ Follow-up actions from previous management review ▪ Changes that could affect the quality management system ▪ Recommendations for improvement ▪ Does the output from the management review include any decisions and actions related to ▪ improvement of the effectiveness of the quality management system and its processes, ▪ improvement of product related to customer requirements, and ▪ resource needs. ▪ What actions have been taken to address the review output?							

APPENDIX II

Process Flowchart Examples



Process Map (Before Revision)



Process Map (After Revision)

APPENDIX III

Document Review Checklist

ELEMENTS		COMMENTS	CHECKLIST
5 Management Responsibility	5.4 Planning	N/A	■ Quality Objective development ■ Measurable quality objective ■ Quality management system planning in transferring to ISO 9001: 2000 system
	5.5 Responsibility, Authority and Communication	N/A	■ Defined and communicated of responsibility and authority ■ Management representative's involvement in process management ■ The method of promoting awareness of customer ■ Internal communication process and method
	5.6 Management Review	N/A	■ 7 Management review inputs ■ 3 Management review output ■ Participants of management review ■ Management review record ■ How to identify the opportunity for continuous improvement ■ Review or amendment to quality policy and quality objective
6 Resource Management	6.1 Provision of Resource	N/A	■ Determining the resource need for implementation/maintenance/continuous improvement of quality system ■ Resource provision during transfer ■ Resource to enhance customer satisfaction
	6.2 Human Resource	■ No responsibility or authority specified to determine the job description and training needs for the **first level manager and second level manager** No method to evaluate the **training effectiveness**	■ Job description ■ Employee skill assessment ■ Training verification ■ Training record
	6.3 Infrastructure	■ No detail specifying the **identification of infrastructure needs** and **on-going maintenance of infrastructure**.	■ Determination of applicable infrastructures ■ Maintenance of infrastructures
	6.4 Work Environment	N/A	■ engineering's published temperature and humidity specifications
7 Production Realization	7.1 Planning of Product Realization	■ Besides the design process, no **production realization planning process**, instead of **production planning**, is clearly defined.	■ The quality objective for new product ■ Process identification/ resource provision for new product ■ Output of production realization planning

ELEMENTS		COMMENTS	CHECKLIST
7 Production Realization	7.2 Customer-related Processes	■ No content specifying the **identification of relevant statutory and regulatory requirements** ■ The method and relevant responsibility of **customer communication** is not available. ■ The contract review process for custom products specified in **Custom Order Procedure**) differs from the one in **Sales Order Entry Procedure** ■ No content pertaining to contact change is available in **Custom Order Procedure** and **Sales Order Entry Procedure**	■ Requirement determination Sys: Standard Product/Custom Item ■ Requirement review content ■ Review & Approval authority ■ Change to contact via Project Change Request
	7.3 Design and Development	■ No clear difference between **Design Verification** vs. **Design Validation** for design control as shown in Design Control Procedure ■ No the condition for conducting **Risk-Production** is available	■ Division A Project Selection/Planning Stage Functional Definition Software/Hardware/End-User Design Project Implementation Unit Test/System Test/Validation Test Critical Design Review ■ Division B Proposal and Planning Phrase Design Implementation Prototype Verification & Validation ■ Project Change Request ■ Preliminary Release Document vs. Engineering Released Document
	7.4 Purchasing	■ Some **supplier approval processes** are not clearly defined. For example, what if the supplier failed to provide 5th perfect delivery? ■ Within system division, no details specify the process pertaining to the **purchase order change** initiated by the company.	■ Quotation request ■ Purchase Ordering ■ Purchase order forecast ■ Supplier Approval ■ Item / Supplier Cross-Reference ■ Material Requirement Planning

ELEMENTS		COMMENTS	CHECKLIST
7 Production Realization	7.5 Production And Service provision	■ No content details the **process validation for production provision** ■ No procedure addressing the **change to production plan and/or work order** ■ How to code and identify **customer-supplied parts** from the purchased parts ■ No specific content addresses **the verification of customer-supplier parts/data/test program and device**	■ Production planning ■ Production provision ■ Work order/Time ticket/Traveler ■ Process equipment maintenance ■ Temperature and humidity specifications ■ INFOFLO System ■ AVANTE System ■ Incorporated Materials Control System ■ Bonding and Branding requirement ■ Servicing provision ■ Customer-supplied parts/data/test program and device ■ Product preservation
	7.6 Control of Monitoring and Measuring Devices	■ How to **reconfirm** the test program in the test device. ■ The **maintenance interval** is not specified in Measuring and Test Equipment, Maintenance and Calibration Procedure	■ Calibration database ■ Calibration label ■ Review of calibration result ■ In-house maintenance instruction
8 Measurement, Analysis and Improvement	8.1 General	N/A	N/A
	8.2.1 Customer Satisfaction	N/A	■ The method of obtaining customer satisfaction information ■ The method of inputting customer satisfaction information into continuous improvement
	8.2.2 Internal Audit	N/A	■ Audit planning addressing the process status and importance ■ Auditor selection ■ Audit implementation and sampling techniques ■ Audit report ■ Follow-up and C&P action
	8.2.3 Monitoring and Measurement of Processes	N/A	■ Identification of processes needed to be monitored and measured ■ The monitoring and measurement method of these processes ■ The monitoring and measurement result as the input of management review

ELEMENTS		COMMENTS	CHECKLIST
8 Measurement, Analysis and Improvement	8.2.4 Monitoring and Measurement of Product	N/A	■ Incoming Inspection Type 1(Critical Item) Type 2 (Non-critical Item) ■ In-process inspection ■ Integration Testing ■ Final QA Testing ■ Review & Approval authority ■ Testing & Inspection Instruction ■ Testing & Inspection record
	8.3 Control of Nonconforming Product	■ No clear distinction of role of **NCRB** and **MRB** ■ The composite of **NCRB/CRB/SRB** is not clearly defined. ■ No control method is specified for **the nonconforming products found during and after assembly** within **semiconductor division** ■ How to input **nonconforming material information** to the **supplier approval** is not addressed ■ The process flow on page 9 of **Material Review Board** is incomplete ■ The format of Design Review and Audit Process is not established by the requirement stipulated in Guidelines for Creating Operating Procedures, Detailed Procedures, and Work Instructions	■ Identification of nonconforming product ■ Method to prevent unintended use or delivery of nonconforming product ■ Determination of identification of different treatment towards nonconforming product ■ Review authority ■ The further action to prevent the recurrence of nonconforming product ■ Record of nonconforming product
	8.4 Analysis of Data	■ Extend the application scope of statistical technique to customer satisfaction and supplier performance	■ Selection of data analysis methods ■ Relevant instruction of data analysis ■ Records of data analysis ■ Contribution of data analysis to continuous improvement
	8.5 Improvement	■ No specific **corrective & preventive action** process is addressed for **semiconductor division**	■ Initiation of corrective & preventive action ■ Determining the cause ■ Determination and implementation of action ■ Review the action taken by relevant authority ■ Corrective & Preventive action record

APPENDIX IV

Documentation Architecture

ELEMENT	TITLE	DOCUMENTS	RELATED PROCEDURES	STATUS
4.1	General requirements			
4.2	Documentation requirements			
4.2.1	General			
4.2.2	Quality Manual	*Quality Manual*		
4.2.3	Control of Documents	***Document Control Operating Procedure***	**CORPORATE** Creating Operating Procedures, Detailed Procedures and Work Instructions Network Backup Procedure Reliability Quality Procedure **Division A** Creating or Changing a Bill of Material Creating an Item Master Drawing Guidelines Procedure Part Naming Convention Part Numbering Guideline Product Changes Procedure Release, Control & Distribution of Product Documentation SOCD Procedure ECO Checking Checking ECO Incorporation Checking New "MD" Drawings Checking New "UA" Drawings **Division B** Engineering Change Procedure Document & Data Control Procedure Receipt & Processing of Document	
4.2.4	Control of Quality records	***Control of Quality Records Operating Procedure***	**Division A** Control of Quality Records Procedure **Division B** Procedure for Records Management	
5	Management responsibility			
5.1	Management commitment	Part of Business Plan		
5.2	Customer focus	Part of Quality Manual		
5.3	Quality Policy	Part of Quality Manual		
5.4	Planning			
5.4.1	Quality objectives			

5.4.2	Quality Management system planning			
5.5	Responsibility, authority and communication			
5.5.1	Responsibility and authority	Part of Quality Manual		
5.5.2	Management representative	Part of Quality Manual		
5.5.3	Internal communication	Part of Quality Manual		
5.6	Management Review	Part of Quality Manual		
5.6.1	General			
5.6.2	Review Input			
5.6.3	Review output			
6	Resource management			
6.1	Provision of resources	Part of Quality Manual		
6.2	Human Resources	***Training Operating Procedure*** (NOTE: replaced by Training Operating Flowchart	ISO 9001 Detailed Training Procedure ISO 9001 Awareness Training Procedure Professional Training Procedure	
6.2.1	General			
6.2.2	Competence , awareness and training			
6.3	Infrastructure	Part of Quality Manual		
6.4	Work Environment	Part of Quality Manual	Temperature Cycle Test Procedure	
7.1	Planning of Product Realization	Part of Quality Manual		
7.2	Customer-related Process	***Contract Review Operating Procedure*** (NOTE: replaced by Customer-Related Flowchart	Project Planning Handbook Custom Order Procedure Sales Order Entry Procedure Contract Review Policy Procedure Test Engineering Evaluation Procedure	
7.2.1	Determination of Requirements Related to the Product			
7.2.2	Review of Requirements Related to the Product			
7.2.3	Customer Communication			
7.3	Design and Development	***Design Control Operating Procedure***	**Division A** C/C++ Code Guideline Conducting Hardware Design Reviews Procedure	
7.3.1	Design and Development Planning			

7.3.2	Design and Development Inputs		Design for Manufacturability Guidelines Mechanical Components	
	Design and Development Inputs		Design for Manufacturability Guidelines of Printed Circuit Boards Testability Guidelines for the Design of Printed Circuit Boards End User Documentation, Design Procedure	
7.3.3	Design and Development Outputs			
7.3.4	Design and Development Review			
7.3.5	Design and Development Verification			
7.3.6	Design and Development Validation			
7.3.7	Control of Design and Development Changes		End User Documentation, Implementation Procedure Functional Specification Procedure Hardware Design Procedure Hardware Implementation Procedure Firmware Documentation Procedure 2001 Operating Procedure for TCS Builds Software Build Procedure Software Configuration Management (SCM) Software Design Procedure Software Implementation Procedure Software Problem Tracking Procedure Software Release Procedure Verification and Validation Procedure MS41XX TCS Readiness Check Procedure MS4205 TCS Readiness Check Procedure **Division B** IC Layout Procedure Phase Release for IC Development Reliability Procedure for Integrated Circuits Semiconductor Design Control Procedure Semiconductor Design Review and Audit Process Procedure Semiconductor IC Implementation Procedure	

7.4	Purchasing	***Purchasing Operating Procedure*** NOTE: System: Add System Purchasing Flowchart into the procedure.	**Division A** Blanket CCA Purchase Order Procedure Item/Supplier Cross Reference Procedure Material Supply Agreement Procedure Order Expediting Procedure Purchase Order Entry Process Procedure Quotation Process Procedure Request for a CCA Quote Procedure Supplier Approval Procedure **Division B** Calendars & Shift Patterns Fabless Operations Procedure for Purchase Requistions Item Master –ECO-BOM Procurement of Wafers from Foundry SemiConductor Fabless Purchasing	
7.4.1	Purchasing Process			
7.4.2	Purchasing Information			
7.4.3	Verification of Purchased Product			
7.5	Production and Service Provision	Part of Quality Manual		
7.5.1	Control of Production and Service Provision	***Process Control Operating Procedure*** NOTE: replaced by Manufacturing Flowchart (the one for semidivision need to be defined) ***Servicing Operating Procedure*** NOTE: Replaced by Product Installation Flowchart	**Division A** CCA's Shared Forecast Procedure Electro-Static Discharge Awareness. Material & Product Handling Procedure End of Year Inventory Procedure Fatal Circuit Card Assembly Procedure Hipot Test Procedure Infoflo Daily & Monthly Closing Checklist Kit Up Procedure Maintain Employee Profile Procedure Material Requirement Planning Procedure Altera Programmable Device Programming Procedure MS4205 PSU Voltage Modifications Procedure Non Active Inventory Review Procedure Non Warranty Return Procedure Paste Up Machine Operating Procedure Production Process Procedure Reflow Oven Operating Procedure Software Copy Procedure	

7.5.2	Validation of Production and Service Provision		Substitute Parts Procedure Temperature Cycle Test Procedure Unisite PAL Programming Procedure Item Master Maintenance & Costing Warranty Period Return Procedure Work Order Release Procedure Work Order Return to Stock Procedure DDCF and CLMP Upgrade Installation Procedure **Division B** Material Requirements Planning (MRP) Fabless Shop Floor Control Procedure Fabless Capacity Planning Procedure Master Product Scheduling (MPS) Logistic Process Flow for Assembly & Test at ASE Process Flow for Final Tes at ASE (Test) Process Flow for Wafer Sort (Probe Test) at ASE (Test) Process Flow for Viper BGA Assembly at ASE Work Centers and Routings Procedure	
7.5.3	Identification and Traceability	***Product Identification and Traceability Operating Procedure*** ***Inspection and Test Status Operation Procedure*** (NOTE: both procedures need to be reviewed and incorporate the parts for division b.)	**Division A** Brother P-Touch PC Label Printer Procedure Product Label Printing Procedure (to include Zebra Label Printing) Smart Label Printing Procedure **Division B** Branding Protocol	
7.5.4	Customer Property	***Customer Supplied Product Operating Procedure***	Handling Customer Supplied Programs & Devices Procedure	
7.5.5	Preservation of Product	***Handling, Storage, Pkg, Preservation and Delivery Operating Procedure*** (5900295-00)	**Division A** Handling and Storage Procedure **Division B** Avante Inventory Control Procedure Fabless Receiving & Shipping Procedure Fabless Engineering Lab Materials	

7.6	Control of Monitoring and Measuring Devices		ESD Audit Procedure Measurement and Test Equip. Maintenance and Calibration Procedure X40 Shop Built Probe Validation and Verification Procedure Shop Built Comparator Skew Test Probe Validation and Verification Procedure	
8.1	General	Part of Quality Manual		
8.2	Monitoring and Measurement	Part of Quality Manual		
8.2.1	Customer Satisfaction	Parts of Data Analysis Procedure		
8.2.2	Internal Audit	***Control of Quality Audits Operating Procedure***	Audit Plan Quality Audit Procedure	
8.2.3	Monitoring and Measurement of Processes	***Control of Quality Audits Operating Procedure*** ***Data Analysis Operating Procedure*** (Note: need to be revised)	Audit Plan Quality Audit Procedure	
8.2.4	Monitoring and Measurement of Product	***Inspection and Test Operating Procedure***	**Division A** Circuit Card Assembly, Test and Inspection Procedure DUT Card Testing Procedure Final Quality Assurance Procedure Incoming Inspection Procedure Incoming Inspection Procedure for the GP DUT Card Mounting Fixture Kit Shortage Procedure **Division B** Assembly & Test Services Procedure	
8.3	Control of Nonconforming Product		**Division A** **Control of Non-Conforming Product Operating Procedure** Deviation Report Procedure [redacted] **Division B** Material Review Board Return Material Authorization Policy (RMA)	

8.4	Analysis of Data	***Data Analysis Operating Procedure*** (Note: need to be revised)		
8.5	Improvement			
8.5.1	Continual Improvement	Part of Quality Manual		
8.5.2	Corrective action		**Division A** **Corrective and Preventive Action Operation Procedures** **Division B** Corrective and Preventive Action Operation Procedure	

APPENDIX V

Internal Audit Plan

INTERNAL AUDIT PLAN

AUDIT OBJECTIVE

To review the progress of quality management system transition and to identify the area for future improvement

AUDIT SCOPE

Division A: Engineering

AUDIT STANDARD

ISO 9001: 2000 Quality Management Systems – Requirements

AUDITOR

System Facilitator

SCHEDULE

TIME	FUNCTIONS	RELEVANT ELEMENTS	AUDITEE
Aug 14 3:00-4:00 PM	Hardware Design	7.3 Design and development	
Aug 15 2:00-3:00 PM	Systems Hardware	7.3 Design and development	
Aug 15 11:00AM-12:00PM	Systems Software	7.3 Design and development	
Aug 12 10:00 –11:00 AM	Product Engineering	7.3 Design and development	

Please note that the following elements would be audited for each function:

4.1 General Requirements
4.2 Documentation Requirements
5.5 Responsibility, authority and communication
6 Resource management
8.4 Analysis of data
8.5 Improvement

INTERNAL AUDIT PLAN

AUDIT OBJECTIVE

To review the progress of quality management system transition and to identify the area for future improvement

AUDIT SCOPE

Division A: manufacturing

AUDIT STANDARD

ISO 9001: 2000 Quality Management Systems – Requirements

AUDITOR

System Facilitator

SCHEDULE

TIME	FUNCTIONS	RELEVANT ELEMENTS	AUDITEE
Aug 13 / 3:00 – 5:00 PM	Manufacturing	7.2 Customer-Related Processes	
Aug 15	Manufacturing	7.1 Planning of Product Realization 7.5 Production and Service Provision	
Aug 20 / 1:00 – 2:00 PM	Material	7.5 Production and Service Provision 8.3 Control of Nonconforming Product	
Aug 21/ 9:00-10:00 AM	Purchasing	7.4 Purchasing	

Please note that the following elements would be audited for each function:

4.1 General Requirements
4.2 Documentation Requirements
5.5 Responsibility, authority and communication
6 Resource management
8.4 Analysis of data
8.5 Improvement

INTERNAL AUDIT PLAN

AUDIT OBJECTIVE

To review the progress of quality management system transition and to identify the area for future improvement

AUDIT SCOPE

Division A: Quality

AUDIT STANDARD

ISO 9001: 2000 Quality Management Systems – Requirements

AUDITOR

System Facilitator

SCHEDULE

TIME	FUNCTIONS	RELEVANT ELEMENTS	AUDITEE
Aug 16 11:00AM-12:00 PM	Monitoring and Measurement	7.2 Customer-related process 7.5 Production and service provision 8.3 Control of nonconforming product	
Aug 20	Q.M.R.	5 Management responsibility 8.2 Monitoring and measurement 8.3 Control of nonconforming product	

Please note that the following elements would be audited for each function:
4.1 General Requirements

4.2 Documentation Requirements
5.5 Responsibility, authority and communication
6 Resource management
8.4 Analysis of data
8.5 Improvement

INTERNAL AUDIT PLAN

AUDIT OBJECTIVE

To review the progress of quality management system transition and to identify the area for future improvement

AUDIT SCOPE

Division B

AUDIT STANDARD

ISO 9001: 2000 Quality Management Systems – Requirements

AUDITOR

System Facilitator

SCHEDULE

TIME	FUNCTIONS	RELEVANT ELEMENTS	AUDITEE
Aug 16/ 1:30-3:00 PM	Contract Review	7.2 Customer-related process 7.5 Production and service provision	
Aug 19	Design	7.3 Design and development 7.5 Production and service provision	
	Purchasing	7.4 Purchasing 7.5 Production and service provision	
Aug 20	Production Planning Scheduling Logistics	7.1 Planning of product realization 7.2 Customer-related process	

TIME	FUNCTIONS	RELEVANT ELEMENTS	AUDITEE
Aug 20	Production Planning Scheduling Logistics	7.5 Production and service provision 8.2 Monitoring and measurement 8.3 Control of nonconforming product	

Please note that the following elements would be audited for each function:

4.1 General Requirements
4.2 Documentation Requirements
5.5 Responsibility, authority and communication
6 Resource management
8.4 Analysis of data

APPENDIX VI

Internal Audit Report

INTERNAL AUDIT REPORT

DEPARTMENTS/FUNCTION	Engineering
AUDITEE	
AUDITOR	System facilitator
AUDIT DATE	Aug 13-15, 2002
AUDIT STANDARD	ISO 9001:2000
PROCESS AUDITEED	7.3 Design and Development 7.5 Production and service provision
FUNCTION AUDITED	Technical Service (7.2/7.3/7.4/ 7.5) Systems Software Engineering (7.2/7.3/7.4/ 7.5) SW Quality & Support (7.2/7.3/7.4/ 7.5) Systems Hardware (7.2/7.3/7.4/ 7.5) Hardware Design (7.2/7.3/7.4/ 7.5)
PROCEDURE AUDITED	Design Control Operating Procedure Hardware Design Procedure Hardware Implementation Procedure Software Design Procedure Software Implementation Procedure

General

This internal audit is aimed to assess the implementation status of ISO 9001: 2001 QMS in the comopany. The audit was conducted for the functions listed above. Any discrepancy found during the audit will be presented for improvement before the initial certification scheduled on Dec. 2-4, 2002.

Summary

The engineering group implement design activities by following the extensive design procedures. It is acknowledge that some of those procedures are currently reviewed and/or revised by the relevant personnel for their relevance to current operation. The clarification and sequence between design verification and validation is somewhat difficult to comply to the

terminologies of ISO 9001: 2000 standard. The possible solution might be: by understanding the difference between those two stages, the engineering group should point out, during the future certification, design verification could not be completed until the design is validated. The selection of evaluation, as well as relevant records of supplier for design function shall be established to ensure the quality of purchased product and service.

Findings:

Minor Nonconformances;

5. The mechanism and methods to determine the applicable statutory requirements, such as CSA standards, are not clearly defined to satisfy customer's requirements. (ISO 9001: 2000 7.2.1)
6. The criteria for selection, evaluation and re-evaluation of suppliers for design function are not established. Records for these evaluations are not available. (ISO 9001: 2000 7.4.1)

Observation:

1. The Software Implementation Procedure should be revised to incorporate the peer review for the software program.

INTERNAL AUDIT REPORT

DEPARTMENTS/FUNCTION	Manufacturing
AUDITEE	
AUDITOR	System facilitator
AUDIT DATE	Aug 13-15, 2002
AUDIT STANDARD	ISO 9001:2000
PROCESS AUDITEED	7.2 Customer-related Process 7.4 Purchasing 7.5 Production and Service Provision 7.6 Control of Monitoring and Measuring Devices 8.2 Monitoring and Measurement 8.3 Control of Nonconforming Product
FUNCTION AUDITED	Materials (7.2/ 7.5) Production (7.5/ 7.6/ 8.2/8.3)
PROCEDURE AUDITED	Customer–related Flowchart Purchasing Operating Procedure Supplier Approval Procedure Manufacturing Flowchart Measurement and Test Equip. Maintenance and Calibration Procedure Control of Nonconforming Product Operating Procedure

General

This internal audit is aimed to assess the implementation status of ISO 9001: 2001 QMS in the comopany. The audit was conducted for the functions listed above. Any discrepancy found during the audit will be presented for improvement before the initial certification scheduled on Dec. 2-4, 2002.

Summary

***Material*:** Customer order is reviewed for company's capability of meeting customer's requirements. According to the sales forecast, production is scheduled. Enough evidence shows that these activities are effectively implemented and documented.
Production: The production is conducted according to the information provided by work order and applicable documents. The production status is clearly indicated and recorded on shop traveler. It is found the test procedure is not controlled. There is no evidence to show that measuring equipments, such as testing fixture, are calibrated or verified.

Findings:

Minor Nonconformances;

7. The current version of MS4205 System Test Procedure which is used by production stuff is B7, contrary to the version in main document registry, which is B. There is no evidence to show that the procedure is approved by the appropriate authorities. (ISO 9001: 2000 4.2.3)
8. The testing fixture is not calibrated or verified at any specified intervals. (ISO 9001:2000 7.6)
9. According to PR5900124 Deviation Report Procedure, Class I deviation is related to an item which deviates from its specification in some aspect of form, fit, or function and requires customer acceptance of the deviation prior to shipment. However, for Class I Deviation Report No. 245 and No. 247, there is no evidence of customer acceptance.

Observation:

1. The corrective action and preventive action for nonconformities found on NCR and Deviation Report recorded in CA/PA Form to follow-up the implementation of these actions for their accuracy and effectiveness. Please refer to Deviation Report No. 245 and NCR. No. 1004.
2. The scope of suppliers which will be evaluated and re-evaluated should be clarified in the relevant procedures.
3. The ISO Supplier List need to be cleared up to make the category of suppliers there be compatible that defined in the Purchasing Operating Procedure.

INTERNAL AUDIT REPORT

DEPARTMENTS/FUNCTION	Quality
AUDITEE	
AUDITOR	System facilitator
AUDIT DATE	Aug 16-20, 2002
AUDIT STANDARD	ISO 9001:2000
PROCESS AUDITEED	5 Management Responsibility 7.6 Control of Monitoring and Measuring Devices 8.2 Monitoring and Measurement 8.3 Control of Nonconforming Product 8.4 Analysis of Data 8.5 Improvement
FUNCTION AUDITED	Inspection (7.6/ 8.2) Quality management Representative (5/8.3/8.4/8.5)
PROCEDURE AUDITED	Quality Manual Control of Quality Audits Operating Procedure Data Analysis Operating Procedure Control of Nonconforming Product Operating Procedure Corrective and Preventive Action Operating Procedure Inspection and Test Operating Procedure Measurement and Test Equip. Maintenance and Calibration Procedure

General

This internal audit is aimed to assess the implementation status of ISO 9001: 2001 QMS in the comopany. The audit was conducted for the functions listed above. Any discrepancy found during the audit will be presented for improvement before the initial certification scheduled on Dec. 2-4, 2002.

Summary

The framework of ISO 9001:2000 quality management system has been set up. Top management use an effective management review to measure the quality performance against quality objectives and communicate relevant information. The internal audit has been implemented as per the annual quality audit plan.
The acceptance criteria and inspection methods are defined and implemented. Calibration of measuring and monitoring devices is being conducted although the testing fixed need to be included.

Findings:

Minor Nonconformances;

10. There is no evidence to show that quality policy and quality objectives were reviewed during previous management review. (ISO 9001: 2000 5.6)

Observation:

1. The quality objectives could be posted on the web in order to inform involved departments.
2. Audit Plan could be resented in the form of notification or timetable instead of a quality document.

INTERNAL AUDIT REPORT

DEPARTMENTS/FUNCTION	Division B
AUDITEE	
AUDITOR	System facilitator
AUDIT DATE	Aug 16-20, 2002
AUDIT STANDARD	ISO 9001:2000
PROCESS AUDITEED	7.2 Customer-related Process 7.3 Design and development 7.4 Purchasing 7.5 Production and Service Provision 8.2 Monitoring and Measurement 8.3 Control of Nonconforming Product
FUNCTION AUDITED	Quality Management Representative (7.2/ 7.4/7.5/8.2/8.3) Purchasing (7.4/8.2/8.3) Engineering (7.3)
PROCEDURE AUDITED	PR5900285-00 Document Control Operating ɔcedure Control of Quality Record Procedure Contract Review Policy Procedure Phase Release for IC development Fabless Operation Procedure for Purachse Requisitions Order Fulfillment Flowchart Data Analysis Operating Procedure

General

This internal audit is aimed to assess the implementation status of ISO 9001: 2001 QMS in the comopany. The audit was conducted for the functions listed above. Any discrepancy found during the audit will be presented for improvement before the initial certification scheduled on Dec. 2-4, 2002.

Summary

The transferring project for Division B is undergoing. It should note that currently there is no customer for the division. All the production, including monitoring and measurement of product, is subcontracted out to the suppliers. Primarily ISO 9001: 2000 quality management system is in place while some specific elements need to be defined.

Findings:

Observation:

3. The external documents, for example, IEEE Project LAN/MAN Standards, and some of internal documents, including Process Flow for Wafer Sort (Probe Test) , are not controlled.
4. The supplier evaluation methods and categories need to be defined in relevant procedures.